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Deposited in DRO:

20 June 2013

Version of attached file:

Published Version

Peer-review status of attached file:

Peer-reviewed

Citation for published item:

Beyleveld, Deryck and Pattinson, Shaun (2000) 'Legal regulation of assisted procreation, genetic diagnosis and gene therapy.', in The ethics of genetics in human procreation. Aldershot: Ashgate, pp. 215-276.

Further information on publisher's website:

Publisher's copyright statement:

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Additional information:

Extracts printed in Lee, R.G Morgan, D., Human Fertilisation and Embryology: Regulating the Reproductive Revolution Oxford: Blackstone, 2001. Cited in the House of Commans (Hansard, 29.11.01, vol. 375, col. 114)

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Legal regulation of assisted procreation, genetic diagnosis and gene therapy

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This report describes the legal regulation of assisted reproduction, genetic diagnosis, and gene therapy within the countries of the EU, and presents a framework for classifying the moral and philosophical issues. It has two parts.

In the first part, we describe the regulation of assisted reproduction, embryo research, cloning, germ-line gene therapy, pre-implantation genetic diagnosis (PGD), and prenatal diagnosis (PND) and abortion. Where legislation exists, it typically prohibits reproductive cloning and germ-line gene therapy, either prohibits non-therapeutic embryo research or subjects it to conditions (such as a 14 day cut-off point), permits abortion and PND, and regulates those assisted reproductive techniques that involve the storage or use of embryos outside the body. However, there is far less convergence on issues such as the permissibility of PGD, and the use of medically assisted reproduction by single women and homosexual couples.

In the second part, we outline a framework for understanding the moral and philosophical issues raised by these regulatory approaches. This framework classifies positions according to the level of non-derivative or intrinsic moral status granted to the embryo or fetus (hereafter embryo-fetus), and the ground offered for this level of intrinsic moral status, thereby highlighting the extent of dissensus in this area.

We conclude by selecting a number of issues that could usefully be addressed by future research.

1 Eligibility criteria for access to assisted reproduction

Table 1

| <i>Country</i> | <i>Legislation</i> | <i>Legislative Criteria</i> | <i>Eligibility</i> | <i>Techniques Subject to the Eligibility Criteria</i> |
|----------------|---|--|--------------------|---|
| Austria | Act No. 275 of 1 July 1992. ² | Must be a married couple or stable heterosexual cohabitee, and be deemed able to provide a satisfactory home for the child (s. 2(1)). ³ All other treatments for infertility must have proved unsuccessful or be considered hopeless. ⁴ | | Artificial insemination, IVF, GIFT, & embryo transfer. ⁵ |
| Belgium | None. ⁶ | Not applicable (hereafter N/A). In practice, assisted reproduction is available for single and lesbian women at more than five Flemish centres. ⁷ | | N/A. No information on the techniques that are subject to eligibility criteria in practice. |
| Denmark | Law No. 499 of 12 June 1996 on Biomedical Research. Law No. 460 of 1997 on Medically Assisted Reproduction. ⁸ | None. ⁹ In practice, treatment is restricted to women who are (a) married or have been cohabiting for 3 years; ¹⁰ (b) under 37 years at the time of entry onto the waiting list; (c) without children; & | | Artificial insemination, IVF, and directly related techniques. ¹¹ There are a few provisions in relation to practitioners concerning information and consent with regard to assisted reproduction |

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| | | (d) have a medical need for treatment. | generally (ss. 23 & 24 Law No. 460). ¹² These provisions are not concerned with eligibility as such. |
| Finland | None. ¹³ | N/A. | N/A. |
| | Proposed legislation exists. ¹⁴ | The proposed legislation restricts access to couples who are married or cohabiting, who are involuntarily childless or whose offspring are likely to inherit a serious disease. Also, the woman must be under 50 years old. ¹⁵ | The proposed legislation covers artificial insemination, IVF, and related techniques. ¹⁷ |
| | | In practice, assisted reproduction is, at present, only offered to married couples and heterosexual cohabitantes. ¹⁶ | No information on the techniques that are subject to eligibility criteria in practice. |
| France | Law 94-654 of 29 July 1994. ¹⁸ | Must be (a) a couple consisting of a man and a woman; (b) alive, i.e., posthumous insemination is prohibited; (c) married or able to prove at least 2 years cohabitation; and (d) of reproductive age (Art. L-152-2). ¹⁹ Treatment is only to be provided to alleviate infertility or to avoid the transmission of a par- | (a) Clinical & biological practices for IVF; (b) transfer of embryos; (c) artificial insemination; and (d) all techniques having similar results that use assisted reproduction outside of the natural process (Art. L-151-1). ²¹ |

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| | | <p>particularly serious disease (Art. 8).²⁰</p> | |
| Germany | <p>Embryo Protection Act 1990.</p> <p>IVF is also covered by guidelines of the Federal Physicians' Chamber.²²</p> | <p>None.</p> <p>The legislation is supplemented by guidelines of the Federal Physicians' Chamber, which require physicians to ensure that the couple are in a stable relationship. These guidelines state that, in principle, access should be restricted to married couples. A specific committee has the power to consider the case of unmarried persons. So, in practice, assisted reproduction is typically offered to married couples only.²³</p> | <p>Any technique involving the <i>in vitro</i> production or use of an embryo (s. 1).</p> |
| Greece | <p>No specific legislation.</p> <p>However, s. 59 of Law 2071 of July 1992 provides for a presidential decree that will regulate the establishment and function of units for artificial fertilisation. This decree has not yet been issued.²⁴</p> | <p>N/A.</p> <p>In practice, assisted reproduction is only offered to married couples and heterosexual cohabitants.²⁵</p> | <p>N/A.</p> <p>No information on the eligibility criteria that are used in practice.</p> |

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| Ireland | None. ²⁶ | N/A. | N/A. |
| | Assisted reproduction is carried out under guidelines of the Medical Council. ²⁷ | Under the guidelines, IVF may only take place with married couples. ²⁸ | No information on the eligibility criteria that are used in practice. |
| Italy | None. ²⁹ | N/A. | N/A. |
| | | Code of Medical Deontology 1995 (which provides guidance for physicians) prohibits insemination outside stable heterosexual couples, after the death of one of the partners, and for elderly women, and prohibits any form of surrogacy. ³¹ Also, under the Code, IVF is only available where there is a medical need for treatment. ³² | The techniques covered by the proposed legislation include IVF, artificial insemination, and related techniques. ³⁵ |
| | | Some clinics in Italy were, however, among the first to treat postmenopausal women. ³³ | In practice, Catholic hospitals, subject to Vatican instruction, do not perform IVF, although some undertake GIFT. ³⁶ |
| | Proposed legislation exists. ³⁰ | Under the proposed legislation, access to assisted reproduction is granted to married or stable heterosexual couples of potentially fertile aged 52 or less (Art. 5). ³⁴ | |

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| Luxem- bourg | None. | N/A. In practice, no assisted reproduction services are available. ³⁷ | N/A |
| Netherlands | Hospitals Act. Decree on IVF Planning 1989. ³⁸ | None. ³⁹ In practice, most IVF centres adopt an age limit of 40 for the woman. ⁴⁰ | No information. No information on the eligibility criteria used in practice. |
| Portugal | None. ⁴¹ A Draft Bill is currently under consideration. ⁴² | N/A. In practice, offered to stable heterosexual couples. ⁴³ No information about the techniques covered by the Draft Bill. | N/A. In practice, there is currently only limited provision for donor insemination, IVF, & GIFT. No information on the eligibility criteria imposed under the Draft Bill. |
| Spain | Law 35 of November 1988. Unimplemented, due to challenge as unconstitutional on enactment. Therefore, the provision of assisted reproduction is currently subject to professional self-regulation. ⁴⁴ | None. Under s. 6 'every woman' is eligible for treatment as long as she provides her written consent, is at least eighteen, and is mentally competent. | Unimplemented law covers IVF, GIFT, artificial insemination, and related techniques. |
| Sweden | Law No. 711 of 14 June 1988 on | Donor insemination and IVF are restricted to | IVF, artificial insemination, and |

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| IVF. | married couples or cohabitees who have been in a relationship for at least 2 years (s. 2 Law No. 1140, & s. 2 of Law 1988, respectively). ⁴⁶ | related treatments. |
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| Law No. 1140 of 20 December 1984 on Insemination. ⁴⁵ | The couple must be unable to have children by natural means. ⁴⁷ | |
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| UK ⁴⁸ | Human Fertilisation and Embryology Act 1990. | Account must be taken of the welfare of any child who will be born or affected as a result of treatment (including the need for a father of any child born as a result of treatment): s. 13(5). |
| | | |
| | | A licence is required for treatments or procedures that involve (a) creation, storage, or use of embryos outside the body (ss. 3(1), 1(2) & 1(3)); or (a) storage or donation of gametes (s. 4(1)). |
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| | | In practice, clinics often use criteria based on age, medical history, duration of infertility, and likelihood of success. ⁴⁹ |
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Increased public awareness of medically assisted reproduction has brought with it a growing demand for these services. This demand, operating in an area of limited resources and great moral controversy, has resulted in access to these services being subject to limitation, often in the form of legislative eligibility criteria.

Table 1 shows diverse legislative criteria.⁵⁰ At one extreme is legislation, like the French legislation, which effectively prohibits the use of assisted reproduction for homosexual couples, single women, non-cohabiting heterosexual couples, surrogate women, and post-menopausal women.⁵¹ Where the couple seeking access to assisted reproduction is unmarried, both the French and Swedish legislation require cohabitation for at least two years, whereas in Austria no specific period of cohabitation is required.

A much more permissive approach has been adopted by the UK Act, which provides for any woman to have treatment, provided that account is taken of the welfare of any child who will be born or affected as a result of

the treatment. This includes consideration of the need for a father of any child born as a result of treatment, which places a heavier burden on non-heterosexual couples, but does not exclude anyone.⁵² Like the Danish legislation, the unimplemented Spanish law is even more permissive, because it explicitly states that 'every woman' is eligible for access to assisted reproduction.

Since the Spanish law has not yet been fully implemented, the *de facto* position in Spain is shaped by non-legislative mechanisms, such as professional guidelines, rather like countries such as Belgium, Greece, Finland, Ireland, Italy, and Portugal, which have no legislation governing access to assisted reproduction. This does not mean that assisted reproduction is available to everyone in those countries. In fact, even where legislative eligibility criteria exist, clinics often have discretionary power to impose additional eligibility requirements. What this means is that, in some countries, harsh *de facto* eligibility criteria apply. For example, in Ireland assisted reproduction is only offered to married couples; in Belgium, Finland, and Greece, access is restricted to married or cohabiting heterosexuals; and in Luxembourg, no such services are offered at all (see Schenker 1997, p. 174).

Overall, the countries of the EU impose three levels of legislative eligibility criteria on those who are not part of a heterosexual couple: either the eligibility criteria exclude such persons from access to assisted reproduction (e.g., France), place harsher requirements on them (e.g., UK), or provide such persons with equal opportunity of access (e.g., Spain). Further, where non-heterosexuals are excluded, there is often a requirement that the heterosexual couple be married or cohabiting for a stated period. And, the eligibility criteria applied in practice are often far stricter than the legislative position would imply.

However, legislative eligibility criteria are not applied to all medical assistance to reproduce. For example, in the UK the need to consider the welfare of any potentially affected child only applies to treatments or procedures that involve the creation, storage, or use of embryos outside the body, or the storage or donation of gametes. This means that many assisted reproductive techniques, such as artificial insemination and gamete intra-fallopian treatment (GIFT) using non-donated gametes, are not subject to legislative eligibility criteria.

Similar limitations apply to the legislation of other countries. For example, the Austrian, Danish,⁵³ French, German, Spanish, and Swedish legislation cover IVF, artificial insemination, and directly related techniques only. This means that many medical responses to infertility are not subject to legislative eligibility criteria, including

- (a) surgical repair of damaged fallopian tubes;
- (b) general practitioner advice; and

(c) the prescription of drugs to maintain and procure pregnancy.

So far we have concentrated on those countries that have legislation governing access to assisted reproduction. Legislative assemblies have not, however, been particularly quick or successful in their attempts to introduce legislation. This is not because assisted reproduction is thought to be uncontroversial or to lack priority. It is because it has proven to be too controversial. For example, since the rejection of the first proposed legislation fifteen years ago, Italy has found itself unable to reach sufficient political consensus for legislative intervention.⁵⁴ Belgium has faced similar difficulties—as illustrated by the refusal of the King to sign the Abortion Act in 1990 (see Schotsmans 1998, p. 2). Ironically, as a result, both Italy and Belgium are, by default, among the most permissive countries in Europe.

In such countries, specific legislation is not likely to be absent for long—for example, Portugal is likely to enact legislation in the very near future—but its present absence does show that assisted reproduction can be successfully regulated by non-legislative means and it shows that the controversiality of assisted reproduction is not simply a matter of the newness of the techniques.

1.2 Embryo research

Table 2.1

| <i>Country</i> | <i>Legislation</i> | <i>Legality of embryo research</i> |
|----------------|---|---|
| Austria | Act on Procreative Medicine No. 275 of 1 July 1992. ⁵⁵ | Embryo research is prohibited, though examination and treatment may be allowed if it is necessary to achieve a pregnancy (Art. 10). ⁵⁶ |

There is a fine for violation.⁵⁷

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| Belgium | None. ⁵⁸ | <p>Embryo research is permitted by default.⁶⁰</p> <p>In practice, only two of the Free Universities undertake embryo research.⁶¹</p> <p>The Committee of Medical Ethics of the National Scientific Research Fund recommends that embryo research should seek to enhance the chance of implantation in the uterus and not be performed after 14 days.</p> |
| | <p>Proposed legislation exists.⁵⁹</p> <p>Law No. 499 of 12 June 1996 on Biomedical Research.</p> | <p>Under Art. 5 of the proposed legislation, the creation of embryos <i>in vitro</i> for scientific research is prohibited, except:</p> <ul style="list-style-type: none"> (a) after a decision of a special commission, conforming to the procedure in Art. 10(1); (b) where the research cannot be done using supernumerary embryos; and (c) all the other provisions of the proposed law are fulfilled. <p>Thus, the creation of embryos for research will be allowed, subject to certain conditions.⁶²</p> |
| Denmark | Law No. 460 of 1997, on Assisted Reproduction, ss. 25–28. | <p>The collection and fertilisation of eggs for research is allowed under certain conditions, such as the agreement of a regional ethics committee.⁶³</p> <p>Research must seek to improve IVF techniques.⁶⁴</p> <p>Fertilised eggs can only be kept <i>in vitro</i> up to 14 days (excluding any periods of cryopreservation).⁶⁵</p> <p>Fertilised eggs subjected to research cannot be transferred to the womb, unless this can happen with no risk of transferring genetic diseases, malformations, etc. (Ch. 4(3)/(4)).⁶⁶</p> <p>Research involving the fusion of genetically different embryos or parts of embryos is not permitted.⁶⁷</p> |

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| Finland | Act on Medical Research No. 488 of 1999. ⁶⁸ | <p>Embryo research is permitted under licence up to 14 days after fertilisation (excluding periods of cryopreservation) (s. 11). The consent of the gamete donors has to be obtained in writing (s. 12).</p> <p>Creation of embryos for research is prohibited. Fertilised eggs that have been subject to research cannot be transferred to the womb, and they are not to be kept alive for more than 14 days after fertilisation. The maximum time limit for cryopreservation of embryos to be used for research is 15 years after which the embryos are to be disposed of (s. 13).</p> <p>Violation of ss. 11 or 13 is sanctioned by up to 1 year imprisonment or a fine (s. 25). Violation of s. 12 is sanctioned by a fine (s. 27).⁶⁹</p> |
| France | Law 94-654 of 29 July 1994 & Decree 97-578 of 28 May 1997, which form part of the Public Health Code. ⁷⁰ | <p><i>In vitro</i> conception of human embryos for research is prohibited (Art. L-152-8).⁷¹</p> <p>In 'exceptional' circumstances, the couple may permit studies to be carried out on the embryo, provided they give written consent, and the studies have a medical purpose, do not impair the embryo, and have the approval of the Comité National d'Ethique (Art. 152-8).⁷² Thus, only non-destructive (therapeutic) research is possible.⁷³</p> <p>Any embryo research must have a direct advantage to the embryo concerned or contribute to the improvement of medically assisted reproduction techniques.</p> <p>Research is limited to the seventh day after fertilisation.⁷⁴</p> <p>Any violation of the law is severely sanctioned (7 years imprisonment and FF 700,000 penalty).⁷⁵</p> |

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| Germany | Embryo Protection Act 1990. ⁷⁶ | <p>It is an offence to</p> <ul style="list-style-type: none"> (a) fertilise a human egg for any purpose other than to start a pregnancy in the woman who produced the egg (Art. 1(2)); (b) use an embryo for any purpose other than its maintenance and healthy development (Art. 2(1)); and (c) separate and use totipotent cells of an embryo for research and diagnosis.⁷⁷ <p>Thus, non-therapeutic embryo research is prohibited.</p> <p>Violation of the law is severely sanctioned by imprisonment up to 3 years or a fine (s. 2).⁷⁸</p> |
| Greece | None. | <p>Embryo research is permitted by default.⁷⁹</p> <p>The Greek Central Council for Health has recommended that research on embryos should be permitted only during the first 14 days from fertilisation (excluding any period of storage).</p> |
| Ireland | <p>The Eighth Amendment to the Constitution (Art. 40.3.3).⁸⁰</p> <p>No specific legislation.</p> | <p>Implicitly prohibited.⁸¹</p> <p>Also, practically impossible because the Medical Council's ethical guidelines require all embryos to be transferred to the woman's body.⁸²</p> <p>No research is being conducted on human embryos.⁸³</p> |
| Italy | None. | <p>Embryo research is permitted by default. Most is performed with the aim of improving the success rate of IVF/GIFT.⁸⁵</p> |
| | Proposed legislation exists. ⁸⁴ | The proposed legislation prohibits the production of embryos for research, along with all non-therapeutic embryo research. ⁸⁶ |
| Luxembourg | None. | No embryo research is being performed. |

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| Netherlands | None. ⁸⁷ | Embryo research is permitted by default. The Health Council has recommended that an embryo should not be grown <i>in vitro</i> beyond 14 days following fertilisation. ⁸⁹ |
| | Proposed legislation exists. ⁸⁸ | The Dutch government is currently preparing a law that is in tune with this recommendation. ⁹⁰ |
| Portugal | None. ⁹¹ | Embryo research is permitted by default. The National Council of Ethics for the Life Sciences has declared that the production of embryos for research is 'ethically unacceptable'. ⁹² |
| Spain | Law 35 of November 1998. | Under the unimplemented law, research is permitted on non-viable embryos up to 14 days after fertilisation, provided the parties concerned give their written consent (ss. 15(1)/(3) & 20). |
| | Challenged as unconstitutional on enactment. ⁹³ | Research can only be conducted on viable embryos if it is applied research of a diagnostic character or if it has a therapeutic or prophylactic purpose, and the non-pathological genetic patrimony is not modified (s. 15)(2)). |
| | | A committee reviews each proposal. ⁹⁴ |
| | | Research must have a purpose laid down in s. 16, such as the improvement of the techniques of assisted reproduction, or increasing knowledge about infertility, gene and chromosome structure, contraception, or the origin of genetic and hereditary diseases. |

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| Sweden | Law No. 115 of 14 March 1991 on Research or Treatment with Fertilised Human Eggs. ⁹⁵ | <p>Surplus embryos may be used for research with the consent of the couple undergoing treatment (s. 1).⁹⁶</p> <p>Embryos that have been subjected to experiments must be destroyed at the end of the 14th day (s. 2).⁹⁷</p> <p>No gametes or embryos that have been the subject of research can be transferred to the woman's body (s. 4).⁹⁸</p> <p>The research must be related to the improvement of IVF techniques and approved by an ethics committee.⁹⁹</p> |
| UK | Human Fertilisation & Embryology Act 1990. | <p>Research on embryos is permitted under licence up to the appearance of the primitive streak or up to 14 days after fertilisation, whichever is the earliest (ss. 1(3)(a) & 1(4)).</p> <p>The creation of embryos specifically for research is permitted under licence (Sch. 2, para. 3(1)).</p> <p>Any research must be 'necessary or desirable' for promoting advances in the treatment of infertility; congenital disease; miscarriage; conception; or gene/chromosome abnormalities (Sch. 2, para. 3(2)).</p> |

Legal regulation of embryo research seeks to balance respect for nascent human life with the benefits that can be produced by advances in scientific knowledge. Given the emotive nature of embryo research, it is no surprise to discover that this regulatory balance is far from uniform. In fact, all possible regulatory approaches can be seen in the EU. This is displayed in Table 2.2 overleaf.

Table 2.2

| <i>Legislative Approach</i> | | <i>Non-Legislative Approach</i> | |
|--|--|---------------------------------|------------------------------|
| <i>Permitted subject to conditions</i> | <i>Prohibited (unless therapeutic)</i> | <i>Permitted by de-fault</i> | <i>Prohibited by default</i> |
| Denmark | Austria | Belgium | Ireland |
| Finland | Germany | Greece | Luxembourg |
| France (exceptionally if non-im-pairing) | | Italy | |
| Spain | | Netherlands | |
| Sweden | | Portugal | |
| UK | | | |

A minority of EU countries—Austria and Germany—prohibit embryo research by legislation; the majority of those with legislation permitting it subject to a number of conditions. For example, the Danish, Finnish, Spanish, Swedish, and the UK legislation permit embryo research up to 14 days after fertilisation, and French legislation permits embryo research which doesn't impair the embryo in 'exceptional' circumstances (but only up to 7 days after fertilisation). After this period, the destruction of the embryo is typically required (France being an exception). Moreover, where embryo research is permitted, the purposes of such research are often prescribed. For example, as table 2.1 shows, the Spanish and UK legisla-tion require embryo research to be for a purpose laid down in the legisla-tion.

Where no specific legislation has been enacted, embryo research is either permitted or prohibited by the legal and cultural tradition of the individual country. For example, in Ireland, the Medical Council's ethical guidelines require all embryos to be transferred to the woman's body (see MacKellar 1997, p. 17), and the Eighth Amendment to the constitution also implicitly prohibits embryo research by declaring that

[t]he State acknowledges the right to life of the unborn and, with due regard to the equal right to life of the mother, guarantees in its laws to respect, and, as far as practicable, by its laws to defend and vindicate that right.

Consequently, in Ireland, no research is being conducted on human embryos. In contrast, in countries such as Belgium, Greece, and Italy embryo research is permitted in the absence of any relevant legislative response.

The European Convention on Human Rights and Biomedicine could have a dramatic effect on these countries. Article 18(1) of this Convention states that

[w]here the law allows research on embryos in vitro, it shall ensure adequate protection of the embryo.

The term ‘adequate protection’ is not defined. So for those countries unable to make a reservation by invoking their pre-existing law under Article 36, signing the Convention might have the effect of hindering (or perhaps even prohibiting) embryo research. Indeed, Article 18(2) states that ‘[t]he creation of human embryos for research purposes is prohibited’.

1.3 Cloning

Table 3

| <i>Country</i> | <i>Legislation</i> | <i>Legislative provisions concerning clonin additional to those addressing embry research</i> |
|----------------|--|---|
| Austria | Act No. 275 of 1 July 1992. ¹⁰⁰ | Cloning is indirectly prohibited. ¹⁰¹ |
| Belgium | None. Legislation cover- ing medical ethics including cloning is currently being con- sidered by Parlia- ment. ¹⁰² | None. |

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| Denmark | Law No. 499 of 12 June 1996 on Bio-medical Research. | Research on, and assisted reproductive treatment with the aim of, producing genetically identical individuals is prohibited, as is nuclear substitution. ¹⁰⁴ |
| | Law No. 460 of 1997 on Assisted Reproduction. ¹⁰³ | |
| Finland | Act on Medical Research No. 488 of 1999. | Conducting medical research for the purpose of facilitating the cloning human beings is a criminal offence and sanctioned by up to 2 years imprisonment or a fine (s. 26). ¹⁰⁵ |
| France | Laws 94-653 and 94-654 of 29 July 1994. ¹⁰⁶ | The embryo research that would be necessary to clone a human being is prohibited (see above, 1.2). Thus, human cloning is implicitly prohibited. ¹⁰⁷ |
| | | The Consultative National Ethics Committee for Health and Life Sciences (CCNE), in its Opinion No. 54 of 22 April 1997, opposed the production of identical human beings. ¹⁰⁸ It also recommended that the ban should be made more explicit when the legislation is revised in 1999. ¹⁰⁹ |
| Germany | Embryo Protection Act 1990 (s. 6). | It is an offence to create an embryo that is genetically identical to another embryo, fetus, or any living or dead person. ¹¹⁰ |
| | | The Act does not define the term 'genetically identical'. ¹¹¹ |
| Greece | None | The Greek Central Council for Health has recommended that assisted reproduction should not be used for the creation of genetically identical human beings. ¹¹² |
| Ireland | None. | The legal position is uncertain. ¹¹³ |

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| Italy | Ministerial Decree of 5 March 1997. ¹¹⁴ Such decrees have legal force for only 90 days unless converted by a vote of Parliament, which did not happen here. ¹¹⁵ | The decree prohibited all forms of experimentation and intervention aimed at (even indirectly) cloning a human or animal. ¹¹⁶ The National Bioethics Committee (CNB) has expressed the view that cloning should be prohibited. ¹¹⁷ |
| Luxembourg | None. | None. |
| Netherlands | None. Proposed legislation exists. ¹¹⁸ | The Dutch government proposes to prohibit the cloning of human beings, but permit the use of cloning techniques in embryo research (before 14 days after conception) in forthcoming legislation. ¹¹⁹ |
| Portugal | None. ¹²⁰ | The National Council of Ethics for the Life Sciences has expressed its opinion that the cloning of human beings is 'ethically unacceptable' and must be prohibited'. ¹²¹ |
| Spain | Law 35 of November 1998 (s. 20), and Title V of the Penal Code (s. 161(2)). ¹²² | It is a criminal offence to create identical human beings, by cloning or other procedures aimed at race selection. |
| Sweden | Law No. 115 of 14 March 1991. | Embryo and oocyte cloning is implicitly prohibited with criminal sanctions. ¹²³ |
| UK | Human Fertilisation & Embryology Act 1990. | Licences are required for the nuclear substitution of an embryo (s. 3(3)(d)), and for the creation of an embryo outside of the body (ss. 3(1)(a) and 1(2)), where an embryo is defined as a live egg that has been fertilised or is in the process of fertilisation (ss. 1(1)(a) and (b)). |

The licensing authority believes that the latter encompasses somatic cell nuclear transfer.¹²⁴

The regulation of human cloning—the deliberate creation of a human being that is genetically identical to another human being or has the same nuclear gene set as another human being—is patchy.¹²⁵ Where legislation within the EU countries does address cloning, it is often influenced by the previous scientific orthodoxy that cloning by nuclear substitution would be done either by replacing the nucleus of an embryo, or replacing the nucleus of an egg with a nucleus from an embryonic cell. In other words, somatic cell nuclear transfer—where the nucleus of an egg cell is replaced with a nucleus of a somatic cell taken from an adult—was not considered to be a possibility before the creation of the sheep named ‘Dolly’.¹²⁶ It follows that the application of the ‘Dolly technique’ to human beings might evade legislative provisions that have been drafted too narrowly.

The UK legislation provides an interesting case. In addition to the licensing requirement imposed on the storage, use, or creation of an embryo outside the body, the UK legislation prohibits the granting of a licence for the nuclear substitution of an embryo. This has led the Human Genetic Advisory Commission (HGAC) and the Human Fertilisation and Embryology Authority (HFEA) to declare that, depending on the method used, cloning is either prohibited or subject to a licensing requirement.¹²⁷ Surely, it might be objected, cloning using the Dolly technique does not involve the creation of an embryo, because an embryo is defined under the Act as ‘a live human embryo where fertilisation is complete’, including ‘an egg in the process of fertilisation’. As Dr. Wilmut and Professor Bulfield put it

[t]he oocyte is an egg but it has not been fertilised and it never is fertilised because the nucleus is transferred to it.¹²⁸

However, in practice, it is very likely that the term ‘fertilisation’ will be judicially construed to include the nuclear substitution of an egg, especially since the HFEA seems to be acting according to this construction of the term.¹²⁹

If fertilisation includes cloning using the Dolly technique, it is interesting to note that

[t]he HFEA’s policy is that it will not license any research which has reproductive cloning as its aim. (HGAC and HFEA 1998a, paragraph 5.4, p. 11)¹³⁰

What this means is that, although cloning a human using somatic cell nuclear transfer is not prohibited in the UK, insofar as it is caught by the legislation, it is just about impossible to do it legally.¹³¹

Another example of legislation that was clearly intended to prohibit cloning is the German Embryo Protection Act (Embryonenschutzgesetz) 1990. Section Six of this Act renders it an offence to create an embryo that is genetically identical to another embryo, fetus, or any living or dead person. Many believe that this provision is sufficient to prohibit cloning by any method (see, e.g., Winter 1997). However, the Act does not define the term 'genetically identical', so it is questionable whether it is wide enough to encompass a clone produced by somatic cell nuclear transfer whose mitochondrial DNA will not be identical to that of the nuclear DNA donor.¹³² Even if it is not, given that the clear intention of this provision was to prohibit cloning by any method, and the fact that this act invokes penal sanctions for activities such as conducting embryo research, it would be extremely unwise to attempt to clone a human being in Germany.

A slightly different position exists in Spain, where the creation of identical human beings—by cloning or any other method—is a criminal offence only where it is aimed at race selection. This provision is clearly wide enough to encompass the development of any new cloning technique, and is particularly interesting because it indicates that the Spanish legislature does not find cloning objectionable *per se*, but instead objects to the racism that it can be used to express.

In general, cloning by nuclear transfer is either prohibited expressly (as in Germany) or implicitly (as in Sweden), or not addressed by the legislature at all (as in Belgium, Greece, the Netherlands, and Luxembourg). It is likely that cloning by any method will soon become illegal in just about all the EU countries, because of the pressure for a global legal ban on the development and use of this technique on human beings. In fact, ten of the fifteen EU countries have now signed the European Convention on Human Rights and Biomedicine and its additional protocol on the prohibition of cloning human beings.¹³³ This protocol makes what was implicit in the Convention¹³⁴ explicit by declaring that

[a]ny intervention seeking to create a human being genetically identical to another human being, whether living or dead, is prohibited.
(Article 1(1))

Since 'genetically identical' is defined as 'sharing with another the same nuclear gene set' (Article 1(2)), somatic cell nuclear transfer is included within this prohibition.

The term ‘human being’ is also not defined in the Convention, so the Netherlands, when it signed the Convention and its protocol, added an interpretative statement stating that

[i]n relation to Article 1 of the Protocol, the Government of the Kingdom of the Netherlands declares that it interprets the term ‘human beings’ as referring exclusively to a human individual, i.e., a human being who has been born.¹³⁵

This statement aims to make room for cloning experiments on embryos within the first fourteen days after fertilisation.

There are a number of other international instruments banning human cloning.¹³⁶ For example, in November 1997, UNESCO published the Universal Declaration on the Human Genome and Human Rights, which stated in Article 11,

[p]ractices which are contrary to human dignity, such as reproductive cloning of human beings shall not be permitted.¹³⁷

Also, the EC has recently passed a Directive on the Legal Protection of Biotechnological Inventions (Directive 98/44/EC), which states in Article 6(2)(a) that ‘processes for cloning human beings’ are unpatentable. This is very likely to act as a disincentive for commercial research and investment into cloning.¹³⁸

1.4 Germ-line gene therapy

Table 4

| <i>Country</i> | <i>Legislative provisions concerning germ-line gene therapy in addition to those addressing embryo research</i> |
|----------------|---|
| Austria | Act on Procreative Medicine 275/1992 prohibits germ-line gene therapy (Art. 9(2)). ¹³⁹ |
| Belgium | None. |
| Denmark | Under Law No. 460 of 1997, eggs and sperm must not be genetically modified. Germ-line gene therapy is not permitted. ¹⁴⁰ |

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| Finland | <p>Act on Medical Research No. 488 of 1999 prohibits research on embryos or gametes for the purpose of developing methods to alter hereditary characteristics, unless it aims to find a cure or to prevent a severe hereditary disease (s. 15). Violation is sanctioned by up to 1 year imprisonment or a fine (s. 25).</p> <p>The working group (set up by the Ministry of Justice) reporting on the use of gametes and embryos in assisted fertilisation had proposed that no gametes or embryos be used in assisted fertilisation where the genetic heritage has been modified.¹⁴¹</p> |
| France | Law 94-654 of 29 July 1994 prohibits germ-line gene therapy and germ-line genetic manipulations. ¹⁴² |
| Germany | Embryo Protection Act 1990 explicitly prohibits germ-line gene therapy (Art. 5(1)/(2).) ¹⁴³ |
| Ireland | None. |
| Greece | None. |
| Italy | None. |
| Luxembourg | No information. |
| Netherlands | None. |
| | The Health Council has recommended a moratorium on human germ-line gene therapy. |
| Portugal | None. |
| Spain | Under s. 15(2)(b) of the unimplemented ¹⁴⁴ Law 35 of November 1998, research on viable embryos can only be conducted where 'the non-pathological genetic patrimony is not modified'. |
| Sweden | Under Law 115 of 1991, research to develop techniques for achieving hereditary alterations (germ-line interventions) is forbidden (s. 2). ¹⁴⁵ |

UK Under the Human Fertilisation and Embryology Act 1990, a treatment licence cannot 'authorise altering the genetic structure of any cell while it forms part of an embryo' (Sch. 2, para. 1(4)), and the same is true of a research licence, 'except in such circumstances (if any) as may be specified in or determined in pursuance of regulations' (Sch. 2, para. 3(4)).

Like cloning by nuclear transfer, germ-line gene therapy—which involves modifying genes so that they can be passed on to future generations—has not yet been successfully performed on humans and has a consensus against its use. Consequently, where germ-line gene therapy and its associated research is addressed by legislation, it is either prohibited or heavily restricted.

The Austrian, Danish, French, German, and Swedish legislation expressly prohibit germ therapy. Even the usually permissive UK Act prohibits germ-line gene therapy, and permits its associated research only where it is allowed by regulation. However, no such regulation currently exists.

Slightly different approaches are adopted by the Spanish and Finnish legislation. The Spanish legislation prohibits embryo research where the non-pathological genetic patrimony is modified, and the Finnish legislation goes further by explicitly permitting germ-line gene therapy where it aims to find a cure for, or prevent, a serious hereditary disease.

Germ-line gene therapy might also be permitted by default in some countries that have no specific legislation. Such countries include Belgium, Greece, and Italy.

Once again, the European Convention on Human Rights and Biomedicine might have an effect on this, because Article 13 declares,

[a]n intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants.

Where a signatory country does not, or is unable to, make a reservation under Article 36 in regard to this provision, it would appear that germ-line gene therapy is prohibited.

As with cloning, the prohibitive inclinations of the European Convention are shared by many other international instruments. For example, Article 24 of the Universal Declaration on the Human Genome and Human Rights states that the International Bioethics Committee of UNESCO should

contribute to dissemination of the principles set out in the Declaration and make recommendations to the General Conference

in particular regarding the identification of practices that *could be* contrary to human dignity, such as *germ-line interventions*'. (Our emphasis)¹⁴⁶

Also, Article 6(2)(b) of the EC Directive on the Legal Protection of Biotechnological Inventions declares that 'processes for modifying the germ line genetic identity of human beings' are unpatentable.¹⁴⁷

1.5 Pre-implantation genetic diagnosis (PGD)

Table 5.1

| <i>Country</i> | <i>Legislation</i> | <i>Legality of PGD</i> |
|----------------|---|--|
| Austria | Act on Procreative Medicine No. 275 of 1 July 1992. | Implicitly forbidden, because under s. 9(1), gametes and pre-implantation embryos ¹⁴⁸ are only permitted to be medically examined and treated to the extent necessary to establish a pregnancy. |
| Belgium | None. ¹⁴⁹ | Permitted by default. A licence is required to establish a centre for genetics. ¹⁵⁰ |
| Denmark | Clinical use: Law No. 460 of 1997, ss. 7 and 21. ¹⁵¹ Research: see Table 2.1. | Implicitly permitted. |

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| Finland | None. | Permitted by default. ¹⁵³ |
| | Proposed legislation exists. ¹⁵² | A working group report, given to the Ministry of Justice in 1997, recommended that the use of assisted reproduction should not be allowed for the purpose of choosing a child's sex or characteristics, except to avoid serious hereditary sex-related disease. ¹⁵⁴ |
| France | Law 94-654 of 29 July 1994. | <p>Authorised by a law that requires the publication of a further decree, which has not been issued. Thus, PGD is currently impossible in France.¹⁵⁵</p> <p>The unimplemented law allows PGD only where</p> <ul style="list-style-type: none"> (a) it is undertaken in a centre licensed by the 'National Commission of Medicine and Biology of Human Reproduction and Prenatal Diagnosis'; and (b) the couple in question provides written consent and has a high probability of producing a child with a severe and incurable genetic defect (Art. 162-17).¹⁵⁶ |
| Germany | Embryo Protection Act 1990. | It is an offence to fertilise a human egg for any purpose other than to start a pregnancy in the woman who produced the egg. ¹⁵⁷ Also, the removal of a totipotent cell is prohibited. ¹⁵⁸ Thus, PGD is implicitly prohibited. |
| Greece | None. ¹⁵⁹ | Permitted by default. ¹⁶⁰ |
| Ireland | None. | Any diagnosis of the pre-implantation embryo is implicitly prohibited, as the Eighth Amendment states, '[t]he State acknowledges the right to life of the unborn and, with due regard to the equal right to life of the mother, guarantees in its laws to respect, and, as far as practicable, by its laws to defend and vindicate that right'. |

| | | |
|-------------|--|--|
| Italy | None. | Permitted by default. |
| Luxembourg | No information. | No information. |
| Netherlands | None. | Permitted by default. ¹⁶¹ Clinical research will fall within the forthcoming Medical Research Involving Human Subjects Act. ¹⁶² |
| Portugal | None. | No information. |
| Spain | Law 35 of November 1998. Since this was challenged as unconstitutional on enactment, the provision of PGD is currently subject to professional self-regulation. | Permitted under the unimplemented law. Assisted reproduction is expressly allowed for the prevention and treatment of illnesses of a genetic or hereditary origin (s. 12(1)). However, genetic selection for non-pathological characteristics is prohibited (s. 13). |
| Sweden | Law No. 115 of 14 March 1991. | Permitted only for the diagnosis of serious, progressive, hereditary disease that leads to premature death and for which there is no cure or treatment. ¹⁶³ |
| UK | Human Fertilisation and Embryology Act 1990. | Permitted. Research licences can be granted for any activity that is 'necessary or desirable' for the purpose of 'developing methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation' (Sch. 2, para. 3(2)(e)). Embryos that have been the subject of research may not be returned to the womb (s. 15(4)). |

Unlike cloning and germ-line gene therapy, there is no consensus against (or, for that matter, in favour of) genetic diagnosis of the oocyte or non-

implanted embryo. Consequently, all four regulatory approaches to PGD are displayed throughout the EU. That is,

Table 5.2

| <i>Legislative Approach</i> | | <i>Non-Legislative Approach</i> | |
|-----------------------------|-------------------|-------------------------------------|------------------------------|
| <i>Permitted</i> | <i>Prohibited</i> | <i>Permitted by default</i> | <i>Prohibited by default</i> |
| Denmark | Austria | Belgium | France (until |
| France (unimplemented law) | Germany | Finland | 1994 law implemented) |
| Spain (unimplemented law) | | Greece | |
| | | Italy | |
| Sweden | | Netherlands | Ireland |
| UK | | Spain (until 1988, law implemented) | Luxembourg |

Countries whose legislation permits PGD vary greatly in the level permissiveness.

The UK licensing authority, in accordance with the permissive legislation under which it operates, has licensed four centres to undertake PGD and its associated research. It has, however, advised the clinics that it licenses that sex selection for social reasons is unacceptable (see HFEA 1998, paragraph 7.20, p. 45).

An example of the restrictive legislative approach can be found in the German Embryo Protection Act (EPA).¹⁶⁴ Under the EPA, it is an offence to fertilise a human egg for any purpose other than to start a pregnancy in the woman who produced the egg. Also, no embryo research is permitted—an embryo being defined as an egg from the time of fertilisation (uniting of the nuclei) and any totipotent cell. This has lead many commentators to suggest that diagnosis of cells after they lose their totipotency is not forbidden by the EPA.¹⁶⁵ Nevertheless, the clear intention of the EPA was to prohibit PGD, and, in 1996, an application to conduct Germany’s first PGD trial was rejected by a local ethics committee on legal grounds.

Whether PGD is acceptable in countries that do not have any specific legislation depends on the individual country’s general legal and cultural

framework. For example, genetic diagnosis of the pre-implantation embryo is implicitly prohibited in Ireland by the Eighth Amendment to the Irish Constitution.

The State acknowledges the right to life of the unborn and, with due regard to the equal right to life of the mother, guarantees in its laws to respect, and, as far as practicable, by its laws to defend and vindicate that right.

In France, the law permits PGD, but its implementation requires the publication of a decree. Therefore,

for the present, although preimplantation diagnosis should be authorized, its practice is currently impossible in France. (Viville *et al.* 1998, p. 1023)¹⁶⁶

The Spanish law, which expressly permits the use of assisted reproduction for the prevention and treatment of illnesses of a genetic or hereditary origin,¹⁶⁷ has also not been implemented. But, due to a different legal and cultural climate, this has not prevented the use of the technique in Spain. Instead, it is performed subject to professional self-regulation. Interestingly, section 13 of the unimplemented law prohibits genetic selection for or against non-pathological characteristics.

Many other European countries do not have laws regulating PGD at all. For example, in Belgium, Greece, Italy, and the Netherlands, PGD is, in effect, permitted by default.

Countries that have signed the European Convention on Human Rights and Biomedicine will, however, have to take account of Article 14, which declares

[t]he use of techniques of medically assisted procreation shall not be allowed for the purpose of choosing the future child's sex, except where serious hereditary sex-related disease is to be avoided.

No country is currently able to make a reservation to this provision based on its pre-existing law.

1.6 Prenatal diagnosis (PND) and abortion

Table 6

| <i>Country</i> | <i>Legislation</i> | <i>Legality of Abortion</i> |
|----------------|---|--|
| Austria | S. 97 of the Penal Code. | <p>Permitted</p> <ul style="list-style-type: none"> (a) within 12 weeks after conception; (b) to protect the mother's health; (c) where the child will probably be severely handicapped; or (d) if the mother was under age at the time of conception.¹⁶⁸ <p>PND is permitted for medical purposes only, with the written consent of the woman.¹⁶⁹</p> |
| Belgium | Law of 3 April 1990. ¹⁷⁰ | <p>Permitted</p> <ul style="list-style-type: none"> (a) before 12 weeks, after counselling, where a doctor is convinced of the pregnant woman's distress and determination; and (b) up to birth, if the pregnancy would threaten the health of the pregnant woman, or there is a substantial risk that the child, if it were born, would have a serious and incurable disease.¹⁷³ |
| Denmark | <p>Pregnancy Act 1973.¹⁷¹</p> <p><i>Research:</i> Law No. 499 of 12 June 1996.¹⁷²</p> | <p>Permitted</p> <ul style="list-style-type: none"> (a) on demand (and for free) within the first 12 weeks; (b) after 12 weeks, where there are social reasons, the cause was rape or incest, or where the child is in danger of hereditary problems or sickness during the embryonic stage; and (c) up to birth, if a serious risk exists for the health of the woman.¹⁷⁴ |

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| | <p><i>Clinical use:</i> Regulated by administrative guidelines.¹⁷⁵</p> | <p>PND is permitted for women over 35 years and women with a risk of hereditary diseases.¹⁷⁶</p> |
| Finland | <p>No information.</p> | <p>Permitted</p> <ul style="list-style-type: none"> (a) before 12 weeks, if two physicians consider that the circumstances of the woman would place considerable strain on her, the pregnancy was caused by rape, the parents are severely limited in their ability to care for the child, or there is reason to believe that the child would be born retarded or would have or develop a serious illness or serious defects; (b) between 12 and 20 weeks of gestation, subject to the permission of the National Board of Medico-Legal Affairs; (c) before 24 weeks, subject to the permission of the National Board of Medico-legal Affairs, if tests show the fetus is seriously ill or has a serious physical deformity, and (d) up to birth, where the woman's life or health is endangered.¹⁷⁷ |
| France | <p>Law 94-654 of 29 July 1994, forming part of the Public Health Code.</p> <p>Decree No. 95-559 of 6 May 1995.</p> <p>Decrees 97-578 and 97-579 of 28 May 1997.¹⁷⁸</p> | <p>Permitted</p> <ul style="list-style-type: none"> (a) before week 10 on demand (Art. L-162-16 of the Public Health Code);¹⁷⁹ and (b) up to birth, if two physicians conclude that the pregnancy endangers the life of the woman, or the child to be born will, most probably, be affected by a particularly serious incurable disorder recognised as such at the time of diagnosis (Art. 13).¹⁸⁰ <p>PND procedures must be preceded by 'medical genetic counselling', fulfilling certain stated aims (Art. L-162-16).¹⁸¹</p> |

| | | |
|---------|---|---|
| Germany | Criminal Code (s. 218). | <p>Abortion is a criminal offence under s. 218, but the physician performing the abortion will not be prosecuted</p> <ul style="list-style-type: none"> (a) up to the first 12 weeks, where the women has had counselling not later than 3 days before the termination (s. 218(a)(1)); (b) up to birth, where there is a risk to the woman's life, or a risk of permanent/serious physical or mental injury to the woman; which could not be averted by any other means (s. 218(a)(2)).¹⁸² In practice, the risk of mental injury to the woman is interpreted to encompass abortion following PND, the emphasis being placed on the pregnant woman rather than the fetus.¹⁸³ <p>The pregnant woman does not commit an offence under s. 218 if the abortion is performed by a physician under 22 weeks, and if the woman has received counselling prior to the abortion (s. 218(a)(4)). Also, under this provision the court can refrain from convicting a pregnant woman, who was experiencing a situation of serious hardship at the time of the abortion.¹⁸⁴</p> |
| Greece | <p>Law 1609/1986 on Abortion.¹⁸⁵</p> <p>Ministerial decision A3B/oik 2799/25.2.87.¹⁸⁶</p> <p>Law 1036/1980 on 'Family Planning'.¹⁸⁷</p> <p>1985 Decision of the Central Council of Health.¹⁸⁸</p> | <p>Permitted where</p> <ul style="list-style-type: none"> (a) the embryo is less than 12 weeks old; (b) there are indications, based on PND, that the embryo to be born will suffer from a serious abnormality and the pregnancy has not passed the 24th week of gestation; (c) the pregnant woman is at risk of death or serious damage to her physical or mental health; or (d) pregnancy results from rape or incest.¹⁸⁹ <p>PND must take place in a state, university, or armed forces hospital.¹⁹⁰</p> |

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| Ireland | The Eighth Amendment to the Constitution (Art. 40.3.3). | The Supreme Court has interpreted the constitution as prohibiting abortion, unless there is a real and substantial threat to the life of the mother. ¹⁹¹ |
| Italy | Legge No. 194/78 of 22 May 1978, Sull'interruzione Volontaria Della Gravidanza (i.e., law on the voluntary interruption of pregnancy). ¹⁹² | Abortion on demand is available within the first 12 weeks and 6 days of pregnancy, after which abortion can only be requested where <ul style="list-style-type: none"> (a) the continuation of the pregnancy or delivery could endanger the woman's life; (b) the fetus has malformations so serious that the woman's psychological or physical well-being is endangered, or if her well-being is endangered by other pathological processes; or (c) the pregnancy is the result of rape.¹⁹³ |
| Luxembourg | Title of legislation unknown. | Permitted <ul style="list-style-type: none"> (a) before 12 weeks, if the pregnancy would threaten the woman's physical and mental health, is the result of rape, or if there is a substantial risk that the child, if it were born, would be very sick or be physically or mentally seriously handicapped; and (b) after 12 weeks, only if two medical doctors ascertain that birth of the child presents a serious risk to the health of the pregnant woman or the child to be born.¹⁹⁴ |
| Netherlands | The Pregnancy Termination Act 1981. ¹⁹⁵ | Permitted up to 24 weeks, if there is a danger to the woman and she has an authentic desire to terminate. ¹⁹⁶ In practice, this permits abortion on demand up to 24 weeks gestation. |

| | | |
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| Portugal | Arts. 140, 141, and 142 of the Penal Code. ¹⁹⁷ | <p>Permitted</p> <ul style="list-style-type: none"> (a) within 12 weeks, if there are medical indications that it will remove the danger of death or of serious and irreversible damage to the pregnant woman's physical or psychological health; (b) up to 16 weeks, if there are serious indications that the pregnancy is the result of crime against 'sexual freedom and self-determination', (c) up to 24 weeks, if there are indisputable medical reasons indicating that the unborn child has a serious incurable disease or congenital defect, and (d) up to birth, if it is 'the only way to remove' the danger of death or of serious and irreversible damage to the pregnant women's physical or psychological health.²⁰⁰ |
| | | <p>Also,</p> <ul style="list-style-type: none"> (e) the physician who approves the abortion cannot perform it; (e) the written consent of the pregnant woman is required; and (f) where the abortion is performed under (c) above, a technical commission of certification is needed.²⁰¹ |
| Spain | <p>Art. 417 bis of Law 9 of 5 July 1985 (part of the Penal Code).¹⁹⁸</p> <p>Royal decree No. 2409 of 21 November 1986.¹⁹⁹</p> | <p>Permitted</p> <ul style="list-style-type: none"> (a) during the first 12 weeks, if the pregnancy is the result of a previously declared rape; (b) during the first 22 weeks, if two specialists who are not performing the abortion diagnose a serious physical or mental abnormality/handicap; and (c) up to birth, to avoid a serious threat to the life or (physical or mental) health of the woman, if stated in a report submitted by a medical specialist who cannot be the physician performing or supervising the abortion.²⁰² |

If an abortion is performed where none of these conditions exist, the woman will not be prosecuted. The person conducting the abortion in such circumstances might, however, be prosecuted (Art. 145).²⁰³

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| Sweden | Abortion Act of 1995. | Permitted (a) up to 18 weeks; (b) up to the end of the 22nd week, if sanctioned by the National Board of Health and Welfare (and only when there is no reason to believe that the fetus is viable); and (c) up to birth, where the pregnancy might gravely imperil the woman's life or health or the fetus is so gravely damaged that it is not viable. ²⁰⁴ |
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All pregnant women are offered information on abortion, and PND.²⁰⁵

| | | |
|---|---|--|
| UK (excluding Northern Ireland). ²⁰⁶ | Abortion Act 1967 (s. 1(1)), as inserted by s. 37 of the Human Fertilisation and Embryology Act 1990. | Permitted (a) up to 24 weeks, where the continuation of the pregnancy will involve risk, greater than if the pregnancy were terminated, of injury to the woman or her family; and (b) up to birth, to save the life of the woman, to avoid permanent injury to her physical or mental health, or to avoid the birth of a severely handicapped child. |
|---|---|--|

The legality of PND is largely dependent on the legality of abortion within particular jurisdictions, and abortion is the most comprehensively regulated area falling within the terms of this report. All but one of the fifteen member states of the EU have specific legislation. Ireland is the exception, as abortion is covered by the constitution rather than legislation, and the constitution (as interpreted by the Supreme Court) prohibits abortion unless there is a real and substantial threat to the life of the pregnant woman.

Thus, with the exception of Ireland, all EU countries have decriminalised abortion where certain conditions are satisfied, up to a specific period of gestation—the most permissive being the legislation of the UK and the Netherlands, which in practice allow abortion on demand up to 24 weeks gestation. In Austria, Belgium, Denmark, Finland, Germany, Greece, Luxembourg, and Portugal, abortion is generally restricted to gestational development of less than 12 weeks. In France the period is ten weeks, in Italy, up to 12 weeks and 6 days, and, in Sweden, the period is up to 18 weeks.

Within these countries, abortion is available for specific reasons beyond this period of gestation. For example, abortion is permitted up to birth to protect the mother's life in all EU countries. For our purposes, it is interesting to see that diagnosis of a serious genetic condition,²⁰⁷ following PND, provides grounds for abortion. In fact, abortion following PND is permitted

- (a) up to birth in Austria, Belgium, Denmark, France, Italy, and the UK;
- (b) up to 24 weeks in Finland, Greece, the Netherlands, and Portugal;
- (c) up to 22 weeks in Spain, and Sweden;²⁰⁸ and
- (e) up to 12 weeks in Luxembourg.

In some countries, use of PND is limited by other legislative conditions. For example, in France and Germany, PND cannot be used for selecting the gender of the child, except in cases of incurable sex-linked hereditary diseases (see MacKellar 1997, p. 10; and Lansac 1996, p. 1847).

In sum, abortion following the diagnosis of a genetic disorder is permitted, subject to specific conditions and gestational development, in all the countries of the EU, with the possible exception of Ireland.

2 Pro-life, pro-choice, and compromise positions

Having reviewed the legal position within the EU countries, we will now develop a framework for analysing the moral and philosophical issues.

In another paper in this volume, one of us offers a three-fold ideal-typical description of the political landscape.²⁰⁹ This classifies the political landscape according to the level of intrinsic moral status granted to the embryo-fetus—that is, according to the moral status that is granted to the human embryo and fetus (hereafter embryo-fetus) by virtue of the characteristics possessed by it.

The first position, the 'pro-life' position, is characterised as granting full moral status to the embryo-fetus from the moment of conception. The second, the 'pro-choice' position, is depicted as granting no intrinsic moral status to the embryo-fetus, until at least birth. The third, the 'compromise'

position, represents the view that the intrinsic moral status of the embryo-fetus increases with gestational development until it obtains full moral status at birth or beyond. In other words, the political landscape is classified according to whether intrinsic moral status is denied to the embryo-fetus (the 'pro-choice' position), granted in full to the embryo-fetus (the 'pro-life' position), or granted on a gradualist scale (the 'compromise' position).

This framework can be applied to the regulation of human reproduction, genetic diagnosis, and gene therapy only insofar as such regulation has implications for the embryo-fetus.²¹⁰ Its application is, however, far from straightforward, because the classification leaves open the possibility that the embryo-fetus might have moral status that is indirectly derived from the moral status of those with intrinsic moral status (hereafter vicarious moral status). This is especially important for the 'pro-choice' position, because it means that this position does not commit its supporters to the idea that anything can be done to the embryo-fetus with impunity.²¹¹

Each of these positions has implications for the regulation of the techniques under discussion. A regulatory structure adopting the 'pro-life' position would characteristically prohibit any non-therapeutic interference with the embryo-fetus. There is one possible exception to this, and that is where the 'pro-life' position is underpinned by a moral theory that aggregates or averages the interests of those with intrinsic moral status. For example, if it is possible to adopt a utilitarian position that grants full moral status to the embryo-fetus from conception, such a position could permit non-therapeutic interference with the embryo-fetus where the interests of a being with full moral status are outweighed by the aggregate (or average of the) interests of other beings with intrinsic moral status. We are not sure whether any such moral theory exists.

A 'pro-choice' regulatory structure would permit such interference, unless its restriction is necessary to protect the legitimate interests of those with full moral status; whereas the 'compromise' position would prohibit such interference except where it is necessary to protect the moral status of those with higher moral status.

For present purposes, we will concentrate on the implications of this classificatory framework for PGD and abortion.

With PGD, it is characteristically intended that the oocyte or pre-implantation embryo will be rejected if the diagnosis were to indicate the presence of an undesired gene or chromosomal abnormality. This is important, because, with the exception of the PGD technique of polar body biopsy on the first polar body, which is performed on a sister cell of the oocyte, all PGD is performed on the pre-implantation embryo. Therefore, with this exception, a non-utilitarian 'pro-life' proponent would be opposed to PGD. The 'pro-life' position's opposition to PGD is strength-

ened where the technique involves the removal and consequential destruction of totipotent cells (as in blastomere biopsy), which some would argue are individual embryos.

A regulatory structure adopting the 'pro-choice' position has the potential to be far more permissive. Since this position does not grant the embryo-fetus intrinsic moral status, it will permit PGD, unless its prohibition is necessary to protect the legitimate interests of those with intrinsic moral status. Such vicarious considerations will restrict or prohibit PGD where it threatens to inflict harm on those with intrinsic moral status that is greater than the harm that will result from denying potential parents (who also have intrinsic moral status) access to PGD. In short, a 'pro-choice' regulatory structure will start from the presumption that PGD is permitted, rebutting this presumption only insofar as the embryo-fetus is shown to have sufficient vicarious moral status.²¹²

The 'compromise' position, sits between the 'pro-life' and 'pro-choice' positions only on the issue of intrinsic moral status. Although the gradualist intrinsic moral status granted to the pre-implantation embryo might be minimal it is still moral status, so the presumption of such a regulatory structure must be against the use of PGD, this presumption only being rebuttable by considerations that seek to protect the moral status of a being with higher intrinsic moral status.

The impact of these three positions on the regulation of abortion is just as complex. A non-utilitarian 'pro-life' position, being the most predictable of the three, will prohibit abortion irrespective of the gestational development of the embryo-fetus except, perhaps, where the life of the mother is in danger. In contrast, the 'pro-choice' position will permit abortion up to the gestational point where the vicarious protection given to the embryo-fetus overrides the mother's right to abort. This point will depend on the strength of the vicarious considerations, the presumption being in favour of permitting abortion. Since pregnancy is potentially very harmful to the mother, the vicarious arguments are less likely to prohibit abortion than PGD. Nevertheless, they are still capable of severely limiting its availability.

The 'compromise' position will, in addition to granting gradualist intrinsic moral status to the embryo-fetus, grant vicarious moral status to the embryo-fetus. The mother will, however, have much greater moral status than the embryo-fetus. Thus, although a 'compromise' regulatory structure would start from the presumption that abortion is prohibited, one would expect abortion to be available at least during early gestation.

2.1 Applying this framework

Before applying this framework to the regulatory positions described in Part One of this report, we need to highlight a number complications.

One complication is that where the protection offered to the embryo-fetus is ‘gradualist’—where gradually greater protection is granted to the embryo-fetus as it approaches birth—this does not necessarily mean that the country in question has adopted a ‘compromise’ position. It might have adopted a ‘pro-choice’ position, because vicarious moral status can also be gradualist. For example, where an embryo-fetus is protected as a means of protecting the sensitivities of those with intrinsic moral status, if these sensitivities increase with the development of the embryo-fetus, the corresponding vicarious protection offered to the embryo-fetus will also increase.

A related complication is that it is possible for the ‘compromise’ position—which starts from a presumption in favour of the embryo-fetus—and the ‘pro-choice’ position—which starts from a presumption against the embryo-fetus—to grant the same degree of protection to the embryo-fetus. However, we suspect that in practice, the regulatory structure will tend towards its underlying presumption. That is, a ‘pro-choice’ regulatory structure, in practice, is likely to be more permissive than a ‘compromise’ regulatory structure.

Bearing in mind these complications, we offer the following line diagram for the values in Table 7 below, where the numbers represent our impression of a location on the scale from the ‘pro-life’ position to the ‘pro-choice’ position. For the reasons just given, the following attributions cannot be described as more than impressionistic descriptions of the tendency of the regulation.²¹³

| | | |
|-----------------|-------------------|-------------------|
| <i>Pro-life</i> | <i>Compromise</i> | <i>Pro-choice</i> |
| 1 | 3 | 5 |

The country tending most strongly towards the ‘pro-life’ position for all the techniques under discussion is Ireland. The Eighth Amendment to the Irish Constitution encapsulates the tenets of the ‘pro-life’ position, as it (implicitly or explicitly) prohibits abortion (except in the extreme circumstances laid down by the constitutional court), embryo research, PGD, and PND.

The other countries are more difficult to categorise in terms of these ideal-typical perspectives. The country tending most strongly towards the pro-choice position is the UK, which permits PGD (with the exception of sex selection for social reasons), permits abortion on demand up to 24 weeks gestation, permits abortion following PND up to birth to avoid the birth of a severely handicapped child, and even permits the deliberate

creation of embryos for research. The UK does, however, limit embryo research to a maximum of 14 days.

Table 7

| PGD | | Embryo Research | | Abortion | |
|---|----------|-----------------|--|----------|---|
| Austria, Ireland | Germany, | 1. | Austria, France, Germany, Ireland | 1. | Ireland |
| | | 2. | Portugal | 2. | France, Italy, Luxembourg, Portugal |
| France (1994 law), Sweden, Spain | | 3. | Sweden, Spain | 3. | Austria, Belgium, Finland, Germany, Greece, Spain |
| | | 4. | Belgium, Finland, Denmark, Greece, Italy, UK | 4. | Sweden, Denmark, Netherlands, UK |
| Belgium, Denmark, Finland, Greece, Italy, Netherlands, UK | | | | | |
| Luxembourg, Portugal | | ? | Luxembourg, Netherlands | | |

The Spanish legislation tends strongly towards the ‘compromise’ position. This legislation permits embryo research only for very limited purposes, restricts abortion during the first 12 weeks to circumstances where the pregnancy is the result of a previously declared rape; and permits abortion following PND during the first 22 weeks only where the embryo-fetus is diagnosed as having a serious physical or mental handicap.

Many of the countries are difficult to classify because they either grant ‘gradualist’ protection—which could be due to granting the embryo-fetus gradualist vicarious moral status or gradualist intrinsic moral status—or are *prima facie* inconsistent. By inconsistent, we mean that some countries seem to have adopted different approaches for different techniques. For

example, the French legislation's prohibition of non-therapeutic embryo research tends towards the 'pro-life' position, but its legislative acceptance of PGD and PND tends more towards the 'compromise' or 'pro-choice' position. Moreover, Austrian and German legislation prohibit embryo research and PGD, suggesting a tendency towards the 'pro-life' camp,²¹⁴ but permit abortion and PND, suggesting a tendency towards the 'compromise' or 'pro-choice' camp. This inconsistency appears to be the result of a clash of positions within the political arena.

Italy represents the most striking example of the effects of interaction between these positions within the political and legislative arenas. In Italy, the Catholic Church's 'pro-life' position has had enough political influence to undermine any 'pro-choice' or 'compromise' legislation in all areas except abortion. It has not, however, been influential enough to enshrine itself in legislation. Consequently, the influence of the 'pro-life' camp has created a *de facto* position that ironically appears to tend towards the 'pro-choice' camp.

Evidently, the regulatory approach is the product of various social, political, legal, and philosophical influences within a particular polity. It might be the result of a political compromise; social, historical, or cultural contingencies; or the adoption of a particular normative position.

Since this is not an empirical project, we will concentrate on analysis of the philosophical perspectives underpinning the adoption of a particular position. In other words, we are not going to examine events within the political process. Instead we will explore the types of philosophical positions that could underpin our ideal-typical pro-life, pro-choice, and compromise positions.

2.2 Grounds for possession of intrinsic moral status

There are a number of potential grounds for the possession of intrinsic moral status. The three that are particularly pertinent for our purposes are those that grant intrinsic moral status to those who are

- (a) sentient; i.e., capable of experiencing pain;
- (b) human; i.e., members of *Homo sapiens*, or
- (c) persons/agents; i.e., able to act for purposes constituting their reasons for action.

A 'pro-life' position must ground possession of intrinsic moral status on a property gained at conception, such as being human or a potential person, if these concepts are defined in a certain way.²¹⁵ Where the latter is taken to be the ground for this position, having such potential must be held to be

sufficient for full moral status, rather than sufficient for moral status that is proportional to the degree of potential.²¹⁶

A 'pro-choice' position must ground possession of intrinsic moral status on a property allegedly not possessed by the embryo-fetus, such as personhood. Obviously, the idea that the embryo-fetus has any intrinsic moral status as a potential, partial, or possible person must be rejected by supporters of the 'pro-choice' position.

The 'compromise' position must be underpinned by a theory that grounds possession of intrinsic moral status on a property/relation that is had in degrees in proportion to gestational development, possession of which in full is held to be sufficient for full moral status. Such positions include those resting intrinsic moral status on degrees of

- (a) possible personhood, i.e., holding that intrinsic moral status is proportional to the degree of evidence supporting the hypothesis that a being is a person;
- (b) sentience; i.e., holding that intrinsic moral status is proportional to the degree of sentience possessed;
- (c) potential personhood; i.e., the view that intrinsic moral status is proportional to the degree of potentiality possessed; or
- (d) approach to an attribute, such as personhood; i.e., holding that intrinsic moral status is proportion to the degree of approach to the relevant attribute.

Even a brief perusal of the national and international debate reveals rhetoric that is capable of simultaneously appealing to more than one of these positions.

At the international level, one only has to look at the pronouncements of international instruments, such as the Council of Europe's Convention on Human Rights and Biomedicine, Article 1 of which demands that parties to it 'protect the dignity and identity of all human beings'. The World Health Organisation has also adopted this type of language in its 1997 resolution, which declares that

[t]he use of cloning for the replication of human individuals is ethically unacceptable and contrary to *human integrity and morality*.
(Quoted in UNESCO 1998. Our emphasis)

Such rhetoric will appeal to those adopting any of the positions outlined above. One reason for this cross-positional appeal is that all the positions that we have outlined grant full intrinsic moral status to adult human beings, and the rhetoric used can suggest that it is the moral status of adult human beings that is being protected. Moreover, the term 'human' is ambiguous as between advocating the view that moral status rests on

membership of the human race (i.e., human in the biological sense) and advocating the view that moral status belongs to persons (i.e., human in a moral sense).

This rhetorical device is standard in the language used by national bodies. For example, the published opinions of the Portuguese National Council of Ethics for the Life Sciences²¹⁷ are loaded with such phrases. In one Report, the National Council asserts that

science does not itself represent a value that may be compared to *human* life and dignity, which it is meant to serve. (National Council of Ethics for the Life Sciences 1995, p. 3. Our emphasis)

In another, the National Council asserts

[t]he cloning of human beings, because of the problems it raises concerning the dignity of the *human person*, the equilibrium of the *human species* and life in society, is ethically unacceptable and must be prohibited. (National Council of Ethics for the Life Sciences 1997b, p. 2. Our emphasis)

In the UK, the HGAC and HFEA (1998a, p. 16) have asserted that cloning

raises serious ethical issues, concerned with *human* responsibility and instrumentalisation of *human beings*. (Our emphasis)

Even where the language appears to be committed to a particular stance, further analysis often reveals more universal appeal. For example, the Warnock Report, which formed the basis of the UK Human Fertilisation and Embryology Act 1990, asserts that 'the embryo of the human species ought to have a special status' (Warnock 1985, paragraph 11.7), albeit less than that of a living child or adult. *Prima facie*, this statement is gradualist, suggesting a 'compromise' position. However, notice the references to 'the human species' (suggesting advocacy of the view that intrinsic moral status is grounded in membership of the human race), and the fact that gradualist conclusions can also appeal to those from the 'pro-choice' camp (due to vicarious considerations).

What this means is that apparent consensus is often not really consensus at all.

Consequently, to some extent, it is naive to look to regulatory structures for an understanding of the various philosophical positions in play. There are of course exceptions—Ireland has clearly adopted the Roman Catholic Church's 'pro-life' position grounding moral status on being human in the biological sense. But the regulatory approaches of other EU countries are

more likely to be the result of political compromises than the adoption of a theoretically pure perspective.

This point is also pertinent to the regulation of medically assisted reproduction. The techniques that legislatures have been concerned to regulate are not those of medical assistance to reproduce as such, but those that are non-traditional or have evoked, or have the potential to evoke, political tension. It is hard to imagine any other ground on which the techniques that are universally subject to legislative eligibility criteria can be distinguished from those that are not.²¹⁸

This difference between the techniques subject to legislative eligibility criteria and those that are not certainly cannot be accounted for on the basis of financial considerations, because, to take one example, surgical repair of damaged fallopian tubes is far more expensive than donor insemination. Moreover, such a position does not seem to serve to protect the intrinsic moral status that the gamete might develop because the imposition of eligibility criteria actually prevent the gamete from developing into a being that will be granted moral status by any of the positions that we have discussed.

The divergence between the EU countries over whether those who are not part of a heterosexual couple should have access to assisted reproduction, must be the result of the same kinds of forces, or factors other than the intrinsic moral status of the embryo-fetus.²¹⁹

In short, looking at the regulatory structures within the EU tells us more about the compromises that have or have not been made in the legislative arena or the socio-political context of the polity, than it does about the underpinning ground for possession of intrinsic moral status. It also highlights the limitations of our attempt to classify the philosophical approaches to these issues. As we stated earlier, not all the philosophical differences reduce to different perspectives on the level of, and ground for possession of, intrinsic moral status. A more comprehensive treatment of this philosophical diversity would have to classify the positions available on issues such as the availability of access to assisted reproduction, the moral status of the pre-conceptus, and the level of moral harm evoked by parental attempts to influence the characteristics of offspring.

Some of the moral issues will be raised in more detail below, but we do not present an overview of the different approaches that could be taken on these issues. Such an overview would take more time and space than we have available here, and require the development of numerous other frameworks.

We do, however, wish to make a few preliminary points. First, a framework for classifying the different approaches on the relevance of marital/relational status and sexual orientation to access to assisted reproduction will have to encompass a number of very diverse perspectives. Posi-

tions on this issue can be underpinned by theories attaching very different values to considerations such as the interests of the child, the significance of the 'standard' family, the interests of minorities, the relevance of sexual orientation, and the relevance of cultural traditions. Creating a framework that accurately captures the essence of this diversity will be no easy task.

Second, since it is usually possible to adopt a position that raises issues falling outside of any particular framework, it will be difficult to construct additional frameworks that have sufficient breath without losing their elucidatory force.

3 Conclusion

In sum, the regulation of assisted reproduction, genetic diagnosis, and genetic therapy across the EU reveals many areas of convergence and divergence. For a start, the EU countries are split between legislative and non-legislative regulatory mechanisms, and between permissive and restrictive approaches. The stringency of the approach adopted does, to some extent, seem to be consistent within each country, so that those countries that are restrictive regarding embryo research are also restrictive regarding PGD, and so on. There are, of course, exceptions. For example, all the EU countries, except Ireland, have adopted permissive legislation governing abortion and PND.²²⁰ Moreover, cloning and germ-line gene therapy have attracted almost universal prohibition.

Analysing these issues in terms of the ideal-typical 'pro-life', 'pro-choice', and 'compromise' positions illustrates the extent to which political compromise has shaped the regulation of the techniques under discussion. This analysis has also revealed a number of potentially fruitful avenues for further study.

On an empirical level, further research could usefully address at least three issues. First, studies are needed to discover the extent to which legislatures are influenced by particular philosophical perspectives. Second, research is needed to determine whether the regulatory approaches adopted within particular countries reflect the attitudes and perceptions held by the general populace. Third, empirical research is often necessary to apply a philosophical perspective because, to take one example, the force of arguments for possession of vicarious moral status rests on empirical hypotheses.

On an analytic level, any deeper philosophical analysis must be conducted from particular philosophical positions rather than groups of philosophical positions. This is not to suggest that any further analysis must adopt one particular theory; we merely suggest that further analysis would be most profitably directed at exploring the implications of particu-

lar philosophical positions one at a time, and, indeed, we are jointly and individually currently undertaking this task with regard to Alan Gewirth's Principle of Generic Consistency (*PGC*).²²¹ As we have argued elsewhere, *in its application*, this rights-based theory grants intrinsic moral status to beings that are possible agents (see Beyleveld and Pattinson 1998 and 2000),²²² and, as a result, belongs to the 'compromise' camp.²²³

There are many moral issues raised by assisted reproduction, genetic diagnosis, and gene therapy, which will be addressed differently by different moral theories.

One issue is whether there is a moral right to reproduce, and if so, what the strength of this right is and whether it includes a right of access to medically assisted reproduction.²²⁴ There is also an issue about whether any such right is purely negative (i.e., imposing duties of non-interference only) or is also positive (i.e., imposing duties of assistance). This issue is important for determining whether access to assisted reproduction ought to be provided by the state.

Another issue requiring consideration rests on the claim that PGD is superior to PND because it avoids the thorny and emotive issue of abortion (see Beyleveld 1999). The validity of such a claim will depend on, *inter alia*, the legitimacy of abortion, the moral status of the oocyte and pre-implantation embryo, and the weight given to the fact that PGD makes it easier to influence the characteristics of one's offspring and more difficult to prevent parents acting for certain motives.

In fact, all of the techniques under discussion enable parents to influence the characteristics of their offspring. This raises the question of whether it is morally legitimate to deliberately manipulate the characteristics of one's offspring before its birth and, if so, whether this applies to all characteristics or is dependent on whether the characteristic is relevant to the possession of intrinsic moral status. Further, there is also the question whether the moral legitimacy of a parental preference for or against characteristics that are irrelevant to the possession of intrinsic moral status is dependent on the characteristic in question. For example, is it relevant that some characteristics—such as Down syndrome and Huntington's disease—hinder the future offspring's range of future purposes without affecting the offspring's possession of intrinsic moral status by virtue of being human, sentient, or an agent?²²⁵ Also, does it matter whether the characteristic in question can be treated, or influenced by other means, such as education, after birth?

Techniques that have yet to be performed on humans, such as cloning by nuclear substitution and germ-line gene therapy, raise other issues. For example, is it morally permissible to attempt to clone a human by somatic cell nuclear transfer given that it took 277 failed attempts to clone Dolly? Is it morally permissible to attempt germ-line gene therapy on humans

given the difficulties highlighted by the 'Beltseville pig' incident, where the genetic switch that was supposed to trigger the production of growth hormone was permanently switched on, resulting in an obese pig with many disorders? In short, the question is: how efficient does a technique have to be before it can legitimately be applied to create a human child?

Given the number of issues evoked by these techniques, it is not surprising to find that the EU displays such great divisions. Indeed, it is surprising to find any consensus at all.

Notes

- ¹ We gratefully acknowledge the help that we received in compiling information on the relevant laws. We are especially grateful to Hille Haker (Zentrum für Ethik in den Wissenschaften, Universität Tübingen) who put a great deal of time and effort into making contacts and collating information on our behalf. Although space prevents us from acknowledging all those who helped, we would particularly like to thank Denis Cusack (Division of Legal Medicine, University College Dublin), Gilda Ferrando (Dipartimento di Diritto dell' Economia d dell' Impresa, Facoltà di Economia), Tina Garanis-Papadatos (Athens School of Public Health, University of Athens), Jennifer Gunning (Cardiff Law School, University of Wales), Ramio Lahti (Faculty of Law, University of Helsinki), Salla Lötjönen (Faculty of Law, University of Helsinki), João Carlos Loureiro (Centro de Direito Biomédico, Universidade de Coimbra), Annamari Hynninen (Faculty of Law, University of Helsinki), Amelia Martín-Uranga (University of Deusto), Sabine Michalowski (Sheffield Institute of Biotechnological Law and Ethics, Sheffield University), Dietmar Mieth (Zentrum für Ethik in den Wissenschaften, Universität Tübingen), Roberto Mordacci (Unità di Etica e Filosofia, Università Vita-Salute San Raffaele), Linda Nielsen (University of Copenhagen), Guido Pennings (Free University of Brussels); Paul Schotsmans (Centrum voor Bio-Medische Ethiek en Recht, Leuven), Nina Schultz-Lorentzen (Institute of Law, University of Copenhagen), Ghislaine van Thiel (Centre for Bioethics and Health Law, Utrecht), and Guido de Wert (Instituut voor Gezondheidsethiek, Maastricht). We also like to thank those who wrote reports, either in a language other than English or on non-EU countries, which we were unable to utilise in this report, including Janusz Balicki (Academy of Catholic Theology, Warsaw), Hans-Georg Koch (Maximum-Planck-Institut für Strafrecht, Freiburg), Josef Kure (Institute of Bioethics, Brno), Alex Mauron (Bioethics Research and Teaching Unit, Geneva Medical School, Centre Médical Universitaire), Judit Sándor (Central European University Budapest), and Günter Virt (Institut für Ethik in der Medizin, Wien). Needless to say we are responsible for any errors and omissions.

- ² See Bernat 1993, p. 494; and MacKellar 1997, p. 2; and Gunning and English 1993, p. 147.
- ³ See Bernat 1993, p. 496; MacKellar 1997, p. 2; Schenker 1997, p. 176; and Gunning and English 1993, p. 147.
- ⁴ See Gunning and English 1993, p. 147.
- ⁵ See Gunning and English 1993, p. 147; and Bernat 1993, p. 496.
- ⁶ See Gunning and English 1993, p. 148. Article 318(4) of the Civil Code does, however, state that a husband cannot dispute his paternity if he has consented to artificial insemination or 'any other act aimed at procreation', except when the conception of a child is not the consequence of such an activity (Schotsmans 1998, p. 1).
- ⁷ Information provided by Guido Pennings.
- ⁸ Information provided by Nina Schultz-Lorentzen.
- ⁹ See Gunning 1998, p. 99.
- ¹⁰ See Nielsen 1996a, p. 310, and Nielsen 1997, p. 127. However, see Schenker 1997, p. 176 for a conflicting view.
- ¹¹ Information provided by Nina Schultz-Lorentzen.
- ¹² Information provided by Nina Schultz-Lorentzen.
- ¹³ Assisted reproduction is, however, subject to the general legislation on health services, which means that only authorised medical personnel can carry out fertilisation treatments (see Hynninen 1998, p. 5).
- ¹⁴ Proposed by a working group report given to the Ministry of Justice in 1997 (see Hynninen 1998, p. 5). The proposed bill has not been introduced into the Parliament and the project has been taken back to the Ministry for re-evaluation following the parliamentary elections in March. (Information provided by Salla Lötjönen.)
- ¹⁵ See Hynninen 1998, p. 5.
- ¹⁶ See Schenker 1997, p. 176. However, a decision was made in May 1999 to prepare legislation that would allow homosexual couples to register their relationship, which might lead to a more liberal attitude towards homosexual couples in the future. (Information provided by Salla Lötjönen.)
- ¹⁷ See Hynninen 1998, p. 5.
- ¹⁸ See Lansac 1996, p. 1843; and Gunning 1998, p. 99.
- ¹⁹ See Lansac 1996, p. 1843; Schenker 1997, p. 176; and Gunning 1998, p. 99.
- ²⁰ See Latham 1998a, p. 95; and Lansac 1996, p. 1843.
- ²¹ See Lansac 1996, p. 1843. 'Confused' artificial insemination (with sperm from more than one man) is forbidden (Article 673-3), donor insemination is allowed only as a 'last resort' (Article 152-6), and donated embryos can only be used 'exceptionally' for couples who cannot conceive without a donor (Article 152-5) (see Sutton 1996, especially p. 43).
- ²² Information provided by Sabine Michalowski.
- ²³ Information provided by Sabine Michalowski.

- ²⁴ See Garanis-Papadatos 1998, p. 1; Gunning and English 1993, p. 172; and Nielsen 1996a, p. 309.
- ²⁵ See Schenker 1997, p. 176.
- ²⁶ See MacKellar 1997, p. 17.
- ²⁷ See MacKellar 1997, p. 17.
- ²⁸ See MacKellar 1997, p. 17; and Schenker 1997, p. 176.
- ²⁹ See, MacKellar 1997, p. 18; Nielsen 1996a, p. 309; Nielsen 1996b, p. 332; and Gunning and English 1993, p. 155.
- ³⁰ The latest proposal is the unified text of 27 January 1998, which has been drawn up by the Commission for Social Affairs of the Chamber of Deputies (see Ferrando 1998, p. 4).
- ³¹ See Ferrando 1998, p. 2; and Schenker 1997, p. 176.
We would like to thank Roberto Mordacci for expanding our understanding of this Code.
- ³² See Ferrando 1998, p. 2; Gunning and English 1993, p. 155; and MacKellar 1997, p. 18.
- ³³ See Nielsen 1996a, p. 309.
- ³⁴ As translated by Ferrando Article 5 grants access to

adult couples of different genders, married or living in stable conditions, with a potentially fertile age and, however, not older than fifty-two. (Ferrando 1998, p. 4)
- ³⁵ See Ferrando 1998, pp. 4–5.
- ³⁶ Gunning and English 1993, p. 157.
- ³⁷ See Schenker 1997, p. 174.
- ³⁸ See Health Council of the Netherlands 1997, especially p. 1 and p. 71.
- ³⁹ See Health Council of the Netherlands 1997, p. 14; and Schenker 1997, p. 174.
- ⁴⁰ See Health Council of the Netherlands 1997, p. 14 and p. 71.
- ⁴¹ However, Decree-Law No. 319/86 of 25 September 1986, covers the collection, manipulation, and preservation of sperm. (See Oliveira 1996, p. 68.)
- ⁴² See National Council of Ethics for the Life Sciences 1997c.
- ⁴³ Information provided João Carlos Loureiro.
- ⁴⁴ It was challenged by the Popular party on enactment.

It was contested that the law was unconstitutional because although it addressed matters of human rights it had not been made an organic law but had been enacted as ordinary law. (Gunning and English 1993, p. 164)
- See also, Gunning 1998, p. 100; and Nielsen 1996a, p. 309. It now appears that implementation of the Act has begun. (Information provided by Jennifer Gunning.)
- ⁴⁵ See Gunning 1998, p. 101.

⁴⁶ See Sutton 1996, pp. 44–45; Nielsen 1997, p. 130; MacKellar 1997, p. 27; Schenker 1997, p. 176; and Gunning and English 1993, p. 164.

⁴⁷ See MacKellar 1997, p. 27.

⁴⁸ The Human Fertilisation and Embryology Act 1990 extends to Northern Ireland (except s. 37 amending the Abortion Act 1967): s. 48.

⁴⁹ See Latham 1998a, p. 94.

⁵⁰ The financial burdens placed on those seeking access should also be noted. In the UK, provision of assisted reproductive services by health authorities is given a low priority, so that only two clinics are wholly funded by the NHS. It has been suggested that, as a result,

Many couples are having to remortgage their homes to pay for treatment.
(Latham 1998a, p. 94)

Clearly, this means that financial means act as *de facto* eligibility criteria for many couples. This is to be contrasted with the situation in France, where couples who fulfil the legislative eligibility criteria ‘will be able to be treated regardless of income for in France treatment for “sterility” is fully reimbursed by the State’ (Latham 1998a p. 96). Similarly, in Germany, social security covers IVF for up to three attempts for married couples (Nielsen 1996a, p. 311).

⁵¹ The French legislation also prevents post-mortem insemination.

⁵² Part 3 of the HFEA’s Code of Practice provides detailed guidance for centres on this requirement to consider the welfare of the child.

⁵³ There are two sections of Law No. 460 dealing with information and consent in relation to assisted reproduction generally. However, these provisions are not concerned with eligibility as such. (Information provided by Nina Schultz-Lorentzen.)

⁵⁴ See Ferrando 1998. In fact

[d]uring the legislative period which ended in 1992, there were 100 bills concerning the regulation of Reproductive Technology, not one of which has been passed into law. (Nielsen 1996, p. 337)

⁵⁵ See Kriari-Catranis 1997, p. 58; and Gunning and English 1993, p. 147 and p. 171.

⁵⁶ See Kriari-Catranis 1997, p. 58; and Gunning and English 1993, p. 148 and p. 171.

⁵⁷ See Bernat 1993, p. 501.

⁵⁸ See, for example, Gunning and English 1993, p. 148.

⁵⁹ See Schotsmans 1998.

⁶⁰ See Gunning and English 1993, p. 148 and p. 172.

⁶¹ See Schenker 1997, p. 181. For a wider discussion, see Gunning and English 1993, p. 148.

- ⁶² Information provided by Guido Pennings.
- ⁶³ See MacKellar 1997, p. 6; EGE 1998a, p. 3; Nielsen 1996b, p. 329; and Gunning and English 1993, p. 172.
- ⁶⁴ See MacKellar 1997, p. 6.
- ⁶⁵ See Gunning and English 1993, p. 151; MacKellar 1997, p. 6; and Nielsen 1996a, p. 140.
- ⁶⁶ See Kriari-Catranis 1997, p. 58; and Gunning and English 1993, p. 151.
- ⁶⁷ See MacKellar 1997, p. 6.
- ⁶⁸ This Act was enacted on 9 April 1999, and comes into force on 1 November 1999. (Information provided by Raimo Lahti.) It was based primarily on the report prepared by a Working Party on Medical Research on Humans, Human Embryos and Fetuses in 1994. On the wider implications of this report, see Lötjönen 1998. See also Hynninen 1998; and EGE 1998a, p. 3.
- ⁶⁹ See Lötjönen 1999, p. 1.
- ⁷⁰ See Lansac 1996; and EGE 1998a, p. 3.
- ⁷¹ See Lansac 1996, p. 1846; Nielsen 1996b, p. 329; and Latham 1998b, p. 236.
- ⁷² The Comité National d’Ethique (National Committee of Reproductive Medicine, Biology and Antenatal Diagnosis) advises the Minister of Health on which clinics to license. (See Lansac 1996, especially p. 1846.). See also, EGE 1998a, p. 3; Nielsen 1996b, p. 329; and Latham 1998b, p. 236.
- ⁷³ See MacKellar 1997, p. 9.
- ⁷⁴ See MacKellar 1997, p. 9; and EGE 1998a, p. 3.
- ⁷⁵ See EGE 1998a, p. 3.
- ⁷⁶ See Gunning and English 1993, p. 154; and EGE 1998a, p. 4.
- ⁷⁷ See Gunning and English 1993, p. 154; Sutton 1996, p. 43; EGE 1998a, p. 4; Bernat 1993, p. 501; Kriari-Catranis 1997, p. 5; and Schenker 1997, p. 181.
- ⁷⁸ See Bernat 1993, p. 501.
- ⁷⁹ See Garanis-Papadatos 1998, p. 1; Gunning and English 1993, p. 172; and Schenker 1997, p. 180.
- ⁸⁰ See MacKellar 1997, p. 17; and *Attorney General v X* [1992] 1. I.R 1.
- ⁸¹ The Eighth Amendment to the Irish Constitution is quoted in the text following table 2.1.
- ⁸² See MacKellar 1997, p. 17.
- ⁸³ See MacKellar 1997, p. 17.
- ⁸⁴ See Ferrando 1998, pp. 4–5.
- ⁸⁵ See MacKellar 1997, p. 18.
- ⁸⁶ See Ferrando 1998, p. 4.
- ⁸⁷ See Gunning and English 1993, p. 172. The EGE Secretariat appears to be mis-informed as it states that the ‘Dutch legislation forbids any research on embryos’ (EGE 1998a, p. 5).
- ⁸⁸ Information provided by Ghislaine van Thiel.
- ⁸⁹ See Health Council of the Netherlands 1997.

90 Information provided by Ghislaine van Thiel.
 91 See Oliveira 1996, p. 68.
 92 See National Council of Ethics for the Life Sciences 1995, especially p. 10.
 93 See Gunning 1998, p. 100. It now appears that implementation of the Act has
 begun. (Information provided by Jennifer Gunning).
 94 See MacKellar 1997, p. 25.
 95 See Sutton 1996, p. 45; and Gunning and English 1993, p. 164 and p. 173.
 96 See Sutton 1996, p. 45.
 97 See Sutton 1996, p. 45; and Gunning and English 1993, p. 164 and p. 173.
 98 See Sutton 1996, p. 45.
 99 See Gunning and English 1993, p. 164.
 100 Information provided by Hille Haker.
 101 Information provided by Hille Haker.
 102 See HGAC & HFEA 1998b, Annexe E.
 103 Information provided by Nina Schultz-Lorentzen. See also, HGAC & HFEA
 1998b, Annexe E; and UNESCO 1998, p. 10.
 104 See UNESCO 1998, p. 10; and HGAC & HFEA 1998b, Annexe E.
 105 See Lötjönen 1999, p. 1.
 106 See HGAC & HFEA 1998b, Annexe E.
 107 See HGAC & HFEA 1998b, Annexe E.
 108 See UNESCO 1998, p. 10.
 109 See HGAC & HFEA 1998b, Annexe E.
 110 See HGAC & HFEA 1998b, Annexe E; and UNESCO 1998, p. 10.

Anyone who artificially creates a human embryo with the same genetic
 information as another embryo, a fetus, an adult human being or a
 deceased person, will be punished by a term of imprisonment up to five
 years or by a fine. (Translated in Winter 1997, p. 191)

111 Information provided by Hille Haker.
 112 See Dalla-Vorgia 1996, p. 281.
 113 Sheikh states that somatic cell nuclear transfer might be affected by the
 Control of Clinical Trials Act 1987 and the Control of Clinical Trials and
 Drugs Act 1990, if they are not 'too vague in their nature to include the
 procedure' (1997, p. 95).
 114 See UNESCO 1998, p. 10.
 115 Information provided by Roberto Mordacci.
 116 See UNESCO 1998, p. 10.
 117 See UNESCO 1998, p. 10.
 118 Information provided by Ghislaine van Thiel.
 119 Information provided by Ghislaine van Thiel.
 120 By implication, see National Council of Ethics for the Life Sciences 1997b,
 p. 2.

- ¹²¹ See National Council of Ethics for the Life Sciences 1997b, p. 2.
- ¹²² Title V of the Penal Code is translated in Lacadena 1996.
- ¹²³ See UNESCO 1998, p. 11; and HGAC & HFEA 1998b, Annexe E.
- ¹²⁴ See the text following Table 3.
- ¹²⁵ We use this definition of cloning throughout. Thus, when we claim that certain countries prohibit cloning we are claiming only that they prohibit techniques involving the deliberate creation of a human being that is genetically identical to another human being or has the same nuclear gene set as another human being.
- ¹²⁶ See the original 'Dolly paper': Wilmut *et al.* 1997. When this paper was published some commentators suggested that Dolly's DNA might have been derived from a 'stem cell', rather than a somatic cell as such. However, this suggestion has been dispelled by the successful cloning of two calves, and 50 mice at two different institutions.
- ¹²⁷ In a jointly written consultation document they state

[t]he nuclear substitution of an embryo, or any cell whilst it forms part of the embryo is expressly prohibited by the HFE Act. Embryo splitting and nuclear replacement of eggs are not expressly prohibited, but as both involve the use or creation of embryos outside the body, they fall within the HFE Act and therefore come under the jurisdiction of the HFEA. (HGAC & HFEA 1998a, paragraph. 5.2, p. 10)

And in the final report they state

[t]he Department of Health and the HFEA have taken Counsel's advice on this issue. As a result, both Ministers and the Authority reject this position and are content that the Act does allow the HFEA to regulate nuclear replacement into an unfertilised egg through its licensing system. (HGAC & HFEA 1998b, paragraph 3.4)

- ¹²⁸ Quoted in Science and Technology Committee 1997, p. xii.
- ¹²⁹ This has lead the House of Commons Select Committee on Science and Technology to declare

[i]t is not satisfactory for issues as momentous as this to be left until they are decided through test cases. We recommend that the Human Fertilisation and Embryology Act should be amended to ensure that the Roslin technique [i.e., the Dolly technique] comes within its scope. (Select Committee for Science and Technology 1997, p. xii)

- ¹³⁰ See also, HGAC & HFEA 1998b, paragraph 3.8, and paragraph 9.2.
- ¹³¹ However, the HGAC & HFEA have recommended that the UK government consider explicitly banning reproductive cloning using any technique (see HGAC & HFEA 1998b, paragraph 9.2).

- ¹³² Jürgen Simon expands upon this point in his commentary on this report, and argues that the German EPA has at least one other flaw.
- ¹³³ The European Convention on Human Rights and Biomedicine opened for signature on 4.4.97, and its additional protocol opened for signature on 12.1.98. The ten EU countries that are signatories are Denmark, Finland, France, Greece, Italy, Luxembourg, the Netherlands, Portugal, Spain, and Sweden. Belgium has not signed it because of the dissensus within public opinion (see Schotsmans 1998, p. 2). Germany has not signed it because it considers it to be too lax, while the UK considers it to be too restrictive.
- ¹³⁴ Provisions implicitly prohibiting cloning include Article 1, which requires parties to the Convention to 'protect the dignity and identity of all human beings', and Article 18, which states that the creation of human embryos for research purposes is prohibited.
- These provisions are important, because it is possible to sign the Convention without signing the protocol. Should a country, such as the UK, which has pre-existing laws on cloning, not wish to prohibit cloning it can make a reservation to these provisions of the Convention by invoking Article 36.
- ¹³⁵ Information provided by Ghislaine van Thiel.
- ¹³⁶ Moreover, the European Commission's former 'Group of Advisers on the Ethical Implications of Biotechnology' has condemned cloning, and so has the World Health Assembly (see HGAC & HFEA 1998b, paragraph 7.2). Jürgen Simon, in his commentary on this report, also points to the European Parliament's March 1997 resolution.
- ¹³⁷ This Declaration was unanimously adopted by the General Conference on 11 November 1997 (see UNESCO 1998).
- ¹³⁸ It might be argued that the disincentive is minimal, because the results of any investment can be protected by other intellectual property mechanisms, such as breach of confidence. However, patent protection has particular appeal to commercial organisations and the condemnatory nature of the political will behind the Directive is itself a disincentive.
- ¹³⁹ See Kriari-Catranis 1998, p. 53.
- ¹⁴⁰ See Rendtorff 1998, especially p. 83.
- ¹⁴¹ See Lötjönen 1999, p. 2.
- ¹⁴² See MacKellar 1997, p. 9.
- ¹⁴³ See Sutton 1996, p. 44.
- ¹⁴⁴ See Gunning 1998, p. 100. It now appears that implementation of the Act has begun. (Information provided by Jennifer Gunning.)
- ¹⁴⁵ See Sutton 1996, p. 45; and Gunning and English 1993, p. 164.
- ¹⁴⁶ The Declaration also declares that all procedures affecting an individual's genome should only be undertaken after 'rigorous and prior assessment of the potential risks and benefits' (Article 5(a)).
- ¹⁴⁷ See also conclusion 6 of the Bilbao declaration, which declares that,

Until scientific advances so allow, and as the exact functions of even one gene are not known, it is prudent to establish a moratorium on the alternation of germinal cells. (Bilbao Declaration 1994, p. 5)

- ¹⁴⁸ The term 'embryo' is not defined under the Austrian legislation. (See EGE 1998b).
- ¹⁴⁹ There is, however, a Higher Council on Human Genetics established under the Crown Order of 7 November 1973 (see Schotsmans 1998, p. 2).
- ¹⁵⁰ See Schotsmans 1998, p. 2.
- ¹⁵¹ Information provided by Nina Schultz-Lorentzen.
- ¹⁵² Information provided by Salla Lötjönen.
- ¹⁵³ See Schenker 1997, p. 178.
- ¹⁵⁴ See Hynninen 1998, pp. 5–6.
- ¹⁵⁵ See Viville *et al.* 1998, p. 1022. This still appears to be true. (Information provided by Jennifer Gunning.)
- ¹⁵⁶ See Viville *et al.* 1998, p. 1022.
- ¹⁵⁷ See MacKellar 1997, p. 10.
- ¹⁵⁸ See MacKellar 1997, p. 10.
- ¹⁵⁹ See Garanis-Papadatos 1998, p. 2.
- ¹⁶⁰ See Garanis-Papadatos 1998, p. 2.
- ¹⁶¹ See Schenker 1997, p. 178.
- ¹⁶² See Health Council of the Netherlands 1997, p. 31.
- ¹⁶³ See MacKellar 1997, p. 27.
- ¹⁶⁴ For a more detailed discussion of the German position vis-à-vis the regulation of PGD, see Jürgen Simon's commentary following this report.
- ¹⁶⁵ However, according to information provided by Hille Haker, some scientists hold that on the third day (when biopsies for PGD are usually made) no totipotent cells exist; others, such as Regine Kollek, consider the cells totipotent at the 6–10 cell stage.
- ¹⁶⁶ See also Fasouliotis 1998, p. 2242. It appears that this is still the situation in France. (Information provided by Jennifer Gunning.)
- ¹⁶⁷ S. 1 of Act 35 of November 1988. S. 12(1) explicitly authorises PGD to test for hereditary diseases in order to treat them or advise against transfer to the womb.
- ¹⁶⁸ See Mandry 1998, p. 34; and Nentwich 1997.
- ¹⁶⁹ Information provided by Hille Haker.
- ¹⁷⁰ See Moulin 1996, p. 27.
- ¹⁷¹ See Petersen 1996, p. 79. Called the Abortion Act by Nielsen 1997, p. 132.
- ¹⁷² Information provided by Nina Schultz-Lorentzen.
- ¹⁷³ See MacKellar 1997, p. 3.
- ¹⁷⁴ See MacKellar 1997, p. 5; Nielsen 1997, p. 132; and Moulin 1996, p. 27.
- ¹⁷⁵ Information provided by Nina Schultz-Lorentzen.

- ¹⁷⁶ See Rendtorff 1998, especially p. 83.
- ¹⁷⁷ See MacKellar 1997, p. 7.
- ¹⁷⁸ See Lansac 1996, p. 1847. For more detailed discussion of Decree No. 97-578, see Jürgen Simon's commentary which follows this report.
- ¹⁷⁹ See Sutton 1996, p. 43.
- ¹⁸⁰ See MacKellar 1997, p. 8; and Lansac 1996, p. 1847.
- ¹⁸¹ See Lansac 1996, p. 1847.
- ¹⁸² Information provided by Sabine Michalowski.
- ¹⁸³ Under the previous law, abortion was permitted for medical indications including hereditary diseases. This provision was removed because it was thought to have eugenic implications. (Information obtained from Schoenke and Schroeder 1997, and Sabine Michalowski.)
- ¹⁸⁴ Information obtained from the same sources as above.
- ¹⁸⁵ See Dalla-Vorgia 1988, p. 4; and Commission of the European Communities 1995.
- ¹⁸⁶ See Dalla-Vorgia 1988, p. 4.
- ¹⁸⁷ See Dalla-Vorgia 1988, p. 3.
- ¹⁸⁸ See Dalla-Vorgia 1988, p. 3.
- ¹⁸⁹ See Commission of the European Communities 1995; and MacKellar 1997, p. 15.
- ¹⁹⁰ See Dalla-Vorgia 1988, p. 4.
- ¹⁹¹ As Finlay CJ put it,

I . . . conclude that the proper test to be applied is that if it is established as a matter of probability that there is a real and substantial risk to the life, as distinct from the health, of the mother, which can only be avoided by the termination of her pregnancy, such termination is permissible, having regard to the true interpretation of Article 40, s. 3, sub-s. 3 of the Constitution [as inserted by the Eighth Amendment to the Constitution]. (*Attorney General v X* [1992] 1 I. R. 1, pp. 53–54)

The 'real and substantial risk to the life' of the mother was held to include the risk of suicide, so that on the facts of *AG v X* the fourteen year old girl, X, was permitted to travel to England for an abortion.

On abortion in Ireland, see also Madden 1997, p. 103; MacKellar 1997, p. 17; and Rendtorff 1998, p. 101.

- ¹⁹² Information provided by Roberto Mordacci.
- ¹⁹³ See MacKellar 1997, p. 18.
- ¹⁹⁴ See MacKellar 1997, p. 19.
- ¹⁹⁵ See Health Council of the Netherlands 1997, p. 50; and Van Thiel 1996, p. 103.
- ¹⁹⁶ See MacKellar 1997, p. 20.
- ¹⁹⁷ Information provided by João Carlos Loureiro.

- ¹⁹⁸ See Gabarrón *et al.* 1997, p. 68.
- ¹⁹⁹ See Gabarrón *et al.* 1997, p. 68.
- ²⁰⁰ See Loureiro 1996, p. 87; and information provided by João Carlos Loureiro.
- ²⁰¹ See MacKellar 1997, p. 23, and information provided by João Carlos Loureiro.
- ²⁰² See Gabarrón *et al.* 1997, p. 68; and MacKellar 1997, p. 25.
- ²⁰³ See Gabarrón *et al.* 1997, p. 68.
- ²⁰⁴ See MacKellar 1997, p. 27. For the position under the previous Abortion Act 1974, see Sutton 1996, p. 4.
- ²⁰⁵ See MacKellar 1997, p. 28.
- ²⁰⁶ Neither s. 37 of the Human Fertilisation and Embryology Act 1990 nor the Abortion Act 1967, extend to Northern Ireland. See s. 48 Human Fertilisation and Embryology Act 1990, and s. 7(3) Abortion Act 1967, respectively.
- ²⁰⁷ This is not to suggest that diagnosis of a serious non-genetic condition cannot legitimate abortion under the legislation of these countries.
- ²⁰⁸ In Sweden, abortion following PND is given no special status under the law.
- ²⁰⁹ See Beyleveld 'The Moral Status of the Human Embryo and Fetus', in this volume.
- ²¹⁰ See below.
- ²¹¹ Vicarious moral status can also increase the protection granted to the embryo-fetus by the 'compromise' position. The effect that vicarious considerations have on the 'pro-life' position is more complex. This depends on the underpinning moral theory. If the 'pro-life' position is underpinned by a deontological moral theory, vicarious considerations can be ignored because the embryo-fetus already has the maximum moral status possible (i.e., full intrinsic moral status). However, if the 'pro-life' position is underpinned by a position which applies an aggregate calculus (such as utilitarianism), the derivative considerations can be decisive in determining our obligations towards the embryo-fetus.
- ²¹² See Beyleveld 1999 for a number of vicarious arguments that can be used to grant protection to the embryo-fetus.
- ²¹³ We are, of course, aware that the possibility of a utilitarian position granting full moral status to the embryo-fetus from conception introduces a level of complexity that our line diagram largely ignores.
- ²¹⁴ Even the title of the German Act, the 'Embryo Protection Act', suggests a 'pro-life' position.
- ²¹⁵ One apparent problem with grounding the 'pro-life' position is that none of the possible grounds seem to appear at conception unless they are defined in an almost question-begging way.
- ²¹⁶ The 'pro-life' position is defined as granting full moral status to the embryo-fetus from the moment of conception. Either this is to be redefined as granting full moral status from at least the moment of conception, or the ground for

such status (whether it is being human or a potential person/agent) cannot be perceived as applying to the unfertilised gamete.

²¹⁷ The National Council is a statutory body set up under Law No. 14/90 of 9 June 1990.

²¹⁸ Exclusion of GIFT using non-donated gametes in the UK Act is particularly interesting because GIFT involves more health risks to the mother than IVF (see Health Council of the Netherlands 1997, p. 30).

²¹⁹ The exclusion of non-heterosexual couples cannot be based on the moral interests of the embryo-fetus, because it is not even plausible to claim that only heterosexual couples make good parents. For example, one study found that the children of single mothers do not suffer from parental failure any more than other children; at most they suffer from the consequences of social and financial problems faced by most single mothers (see Golombok and Rust 1986, especially p. 182). Moreover,

[t]he only British study in this area (which supports similar studies in the U.S.) [Golombok, Spencer, and Rutter 1983, 55] reports no statistically significant differences in psychiatric state between children with lesbian or heterosexual mothers and the incidence of disorder was similar to that found in heterosexual two-parent families. (Madden 1996, p. 16)

²²⁰ As we pointed out above, the French legislation appears to be inconsistent because it prohibits non-therapeutic embryo research but permits PGD. However, unlike Austria and Germany, the French legislation has adopted an approach that is consistent between PGD and PND.

²²¹ Gewirth (1978) presents the argument to the *PGC*, which is defended against objections published up to 1990 in Beyleveld 1991.

²²² See also Beyleveld 'The Moral Status of the Human Embryo and Fetus' in this volume.

²²³ See Beyleveld *ibid.* Also, on the application of the *PGC*, see Beyleveld, Quarrell, and Toddington 1997.

²²⁴ For a discussion of this issue from a Gewirthian perspective, see Pattinson 1998.

²²⁵ See Beyleveld, Quarrell, and Toddington 1997 for a Gewirthian perspective on some of the issues raised by this question.

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